91-1987

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IN THE
Supreme Court of the United States
October Term, 1992

GARY TURPIN AND BETTY TURPIN,
INDIVIDUALLY AND AS PARENT AND NATURAL
GUARDIAN OF BRANDY TURPIN, A MINOR,
Petitioners,

v.

MERRELL DOW PHARMACEUTICALS, INC.,
Respondent.

PETITION FOR WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

PETITION FOR WRIT OF CERTIORARI

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QUESTIONS PRESENTED

1. Whether Fed. R. Civ. P. 56(e) and the Seventh Amendment permit federal courts to grant summary judgment on a contested factual issue, and take the issue from the jury, by weighing the relative credibility of the opinions of competing qualified experts.

2. Whether the lower federal courts possess inherent judicial power to impose nationwide uniformity on scientific issues common to diversity cases arising under the law of the 50 States, supposedly to prevent "inconsistent" verdicts on these scientific issues.

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OPINIONS BELOW

The opinion of the United States Court of Appeals for the Sixth Circuit, affirming the district court's grant of summary judgment for respondent, is reported at 959 F.2d 1349, and is reprinted as Appendix A, at page A1. (References to the appendices bound with this Petition are styled "A___"). The memorandum decision and order of the United States District Court for the Eastern District of Kentucky, from which appeal was taken, is reported at 736 F. Supp. 737, and is reprinted as Appendix B, at page A23.

JURISDICTION

The decision of the Court of Appeals was announced on March 11, 1992. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

CONSTITUTIONAL AND STATUTORY PROVISIONS

Rule 56 of the Federal Rules of Civil Procedure provides, in relevant part, that:

> (c) . . . The judgment sought shall be rendered forthwith if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law. . . .
>
> (e) . . . When a motion for summary judgment is made and supported as provided in this rule, an adverse party may not rest upon the mere allegations or denials of the adverse party's pleading, but the adverse party's response, by affidavits or otherwise provided by this rule, must set forth specific facts showing that there is a genuine issue for trial. If the adverse party does not so respond, summary judgment, if appropriate, shall be entered against the adverse.

The Seventh Amendment to the United States Constitution provides that:

In Suits at common law, where the value in controversy shall exceed twenty dollars, the right of trial by jury shall be preserved, and no fact tried by jury, shall be re-examined in any Court of the United States, than according to the rules of the common law.

STATEMENT OF THE CASE

1. This is a products liability case governed by Kentucky substantive law. The facts leading to the lawsuit are not disputed. Petitioners Gary and Betty Turpin are the parents of Brandy Turpin, who was born on February 27, 1982, with deformities to her hands and feet. The Turpins filed suit against respondent Merrell Dow Pharmaceuticals, Inc. ("Merrell") in the United States District Court for the Eastern District of Kentucky, alleging that Brandy's limb defects had been caused by Bendectin, a prescription anti-nausea drug marketed by Merrell, which Brandy's mother had taken during the limb-development phase of pregnancy. No identifiable risk factor other than ingestion of Bendectin was present. (A2.) Seven experts put forward their testimony in support of the Turpins' allegation that Bendectin had caused Brandy's limb defects.

2. After preliminary discovery, Merrell moved for summary judgment in the District court on the issue of causation. In its filing under Fed. R. Civ. P. 56(c) Merrell claimed that there exists no scientific proof that Bendectin causes birth defects, and therefore that it could not have caused the birth defects at issue in the case. The sole admissible evidence introduced by Merrell in support of this proposition consisted of the conclusions of three expert witnesses whose affidavits were submitted to the District court. The Turpins conceded that these experts were qualified to state an opinion concerning the effect of Bendectin on birth defects.

Dr. Steven H. Lamm, a pediatrician, stated that in his view Bendectin has not been statistically associated with birth defects generally and therefore: "[I]t is also my opinion to a reasonable degree of medical and scientific certainty that Betty Turpin's ingestion of Bendectin during pregnancy did not cause the

congenital limb malformations of her daughter, Brandy." Aff. ¶ 10(g). Dr. Bryan D. Hall, a medical professor and pediatrician, concluded: "[I]t is my opinion to a reasonable degree of medical and scientific certainty that maternal ingestion of Bendectin is not associated with, and does not cause, limb reduction defects generally, and did not cause Brandy Turpin's limb defects." Aff. ¶ 12. Dr. John W. Greene, Jr., a medical professor and obstetrician/gynecologist, opined somewhat less precisely: "[T]here is insufficient evidence to conclude that Bendectin is associated with birth defects in general, or limb disorders or amniotic band syndrome specifically." Aff. ¶ 9.

These ultimate statements of opinion about causation, standing alone, constituted admissible evidence, because Rules 704(a) and 705 of the Federal Rules of Evidence permit qualified experts to state their opinions on an ultimate issue of fact without disclosing the facts or data underlying the opinion. Each expert sought to enhance the credibility of his opinion by including several pages of elaboration about the reasoning that had led him to his ultimate opinion concerning non-causation. This reasoning focused primarily on epidemiological data collected and published in medical and scientific journals, and seeking to estimate the effect of Bendectin on mass populations. (*See* A8-A14.) These and other sources of data, however, were not entered into evidence as proof of non-causation. They were not part of the admissible summary judgment record at all. Rather, the experts freely and informally referred to these outside sources as permitted by Rule 703 of the Federal Rules of Evidence, which functions as "the expert testimony exception to the hearsay rules." *United States v. Unruh*, 855 F.2d 1363, 1376 (9th Cir. 1987), *cert. denied*, 488 U.S. 974 (1988).[1]

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[1] *See also Rogers v. Raymark Industries, Inc.*, 922 F.2d 1426, 1429-30 (9th Cir. 1991) ("an expert opinion may be based on any type of evidence commonly used in the field"); *United States v. Lundy*, 809 F.2d 392, 395-96 (7th Cir. 1987) ("hearsay and third-party observations that are of a type normally relied upon by an expert in the field are properly utilized by such an expert in developing an expert opinion"); *Clinchfield Railroad Co. v. Lynch*, 784 F.2d 545, 553-544 (4th Cir. 1986) (after Rule 703 showing that facts or data are "regularly relied upon" by experts in the field,

As required by Fed. R. Civ. P. 56(e), the Turpins opposed summary judgment with affidavits from seven expert witnesses, skilled in several relevant scientific and medical disciplines. Merrell readily conceded that each of the seven experts was qualified to state an opinion concerning the effect of Bendectin on birth defects. One of the Turpins' experts, Dr. John Palmer, a medical professor and physician specializing in pharmacology, concluded: "I have also examined the medical records pertaining to Brandy Turpin and it is my opinion within a reasonable degree of medical certainty that Bendectin was taken at the period of time so as to [affect] the cells that would produce the normal limb structure in Brandy Turpin and that Bendectin did cause the limb defects from which she suffers." Aff. ¶ 14. Under Fed. R. Evid. 704(a) and 705 this ultimate statement of opinion about causation from a qualified expert, standing alone, was admissible proof of causation.

The credibility of Dr. Palmer's opinion was enhanced, however, by several pages of elaboration on his reasoning and on his consideration of data from four standard sources of information about whether particular substances cause birth defects: (1) *in vitro* animal tests on animal cells, (2) *in vivo* animal tests on live animals, (3) analysis of chemical structure, and (4) analysis of data contained in the same published epidemiological studies considered by Merrell's experts. As with the sources of data relied on by Merrell's experts, these sources were not themselves entered into evidence. Rather, Dr. Palmer referred to these outside sources pursuant to Fed. R. Evid. 703. The Turpins also submitted the affidavits of six other concededly qualified experts drawn from a variety of fields related to birth defects, including teratology (the study of substances that produce malformations in human fetuses), pathology, chemistry, developmental biology, pharmacology, toxicology, embryology and dysmorphology and epidemiology. These six affidavits demonstrated to the district court how the Turpins would further enhance the credibility of Dr. Palmer's ultimate opinion at trial.

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questions going to weight should be "'attacked by cross examination and refutation'").

Each of these six experts (and particularly Professor Stuart Newman, a medical professor and leading teratologist) elaborated on Dr. Palmer's reasoning, and rebutted the reasoning of Merrell's three experts, using one or more of the sources of information. (*See* A14-A19; *see also* A25-27.)

3. On this record the District court granted summary judgment. The District court's primary ground was that all of the Turpins' expert testimony was "inadmissible under Fed. R. Evid. 703." (A35.) Here the District court cited decisions rendered by the D.C. Circuit and the First Circuit in Bendectin cases involving different plaintiffs and different evidence, interpreting Rule 703 as providing a tool for courts to scrutinize the weight of an expert's reasoning and exclude any expert opinion that is deemed to lack an "adequate" foundation. (*See* A27-A31 (citing *Richardson v. Richardson-Merrell, Inc.*, 857 F.2d 823 (D.C. Cir. 1988), *cert. denied*, 110 S. Ct. 218 (1989), and *Lynch v. Merrell-National Labs.*, 830 F.2d 1190 (1st Cir. 1987)).) In these cases, the District court noted, courts "looked behind the expert's ultimate conclusion that Bendectin causes birth defects and analyzed the adequacy of its foundation" and decided that the reasoning employed was "'not capable of proving causation in the face of the overwhelming body of contradictory epidemiological evidence.'" (A28 (quoting *Richardson*).) This supposedly overwhelming body of epidemiological evidence consisted of more than 30 "studies" considering the effects of Bendectin, none of which considered in isolation proved causation with "statistical significance," i.e., 95% certainty. (A32-A33. *See* A14-A16 (Sixth Circuit's criticisms).)[2]

The District court ruled in the alternative that "even if admissible, these opinions only support the conclusion that it is

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[2] Concerning Merrell's allegation that there are more than 30 "studies" on Bendectin, only if one could describe any article that *mentions* Bendectin as a "study" would this be true. In fact very few human epidemiological studies meaningfully focusing on Bendectin exist. Fewer than 15,000 women who took Bendectin during their pregnancy were ever included in any epidemiological study involving Bendectin.

possible that Bendectin is teratogenic," and that "[e]ven viewing the record in the light most favorable to the nonmoving party," the plaintiffs have failed to meet their burden." (A35.) The District court did not address Dr. Palmer's explicit opinion that Bendectin had caused Brandy's limb defects, nor did the District court explain why, if Dr. Palmer's opinion was admissible, the court enjoyed the power to evaluate the credibility of that opinion against other opinions and thereby displace that traditional jury function.

4. In the Sixth Circuit the Turpins attacked the District court's exclusion of their expert testimony under Rule 703 on the ground of legal error. They argue that Rule 703 is a permissive rule designed to streamline expert testimony by allowing experts to refer to all sources of information normally relied upon in their fields, and that in enacting Rule 703 Congress did not empower courts to weigh the relative credibility of competing expert opinions. The Sixth Circuit had long before accepted this statutory construction of Rule 703.[3] It therefore assumed that the Turpins' expert testimony was admissible under Rule 703, and stated that the case "should be decided on the rules of the sufficiency of evidence of causation on summary judgment, as Judge Siler held below in the alternative." (A7).

In addressing the record's evidentiary conflict between, on the one hand, Merrell's three experts claiming that Bendectin is incapable of causing any birth defects and, on the other hand, the Turpins' seven experts together supporting the conclusion that Bendectin had caused Brandy's limb defects, the Sixth Circuit below considered and answered two general legal issues of importance to many cases in the federal court system, and on which several circuits are in substantial conflict.

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[3] *See Mannino v. International Manufacturing Co.*, 650 F.2d 846, 851 (6th Cir. 1981) ("[t]he purpose of Rule 703 is to make available to the expert all of the kinds of things that an expert would normally rely upon in forming an opinion, without requiring that these be admissible in evidence," and through it "the law is catching up with the realities of professional life"); *see also Kingsley Associates, Inc. v. Del-Met, Inc.*, 918 F.2d 1277, 1286-87 (6th Cir. 1990).

First, the Sixth Circuit asked "whether a court should judge for itself the validity of the reasoning process by which various competing qualified experts have reached their conclusions or should instead leave that question for the jury." (A1). In other words, upon the presentation of qualified, admissible expert opinion testimony establishing a conflict over factual issue under Fed. R. Civ. P. 56, the Sixth Circuit asked whether a court may proceed to judge the credibility of the opinions itself rather than leaving that function to the jury. It held that: "[A]lthough judges should respect scientific opinion and recognize their own limited scientific knowledge, nevertheless courts have a duty to inspect the reasoning of qualified scientific experts to determine whether a case should go to the jury." (A1-A2).

Second, the Sixth Circuit considered the relevance of a pattern of inconsistent jury verdicts nationwide to the issue of how closely a court should scrutinize, on summary judgment, the credibility of competing expert opinions. The court left no doubt as to its concern about this phenomenon:

> For a judicial system founded on the premise that justice and consistency are related ideas, the inconsistent results reached by courts and juries nationwide on the question of causation in Bendectin birth defects cases are of serious concern.

(A1). The Sixth Circuit explained that because of similar evidence, even though different plaintiffs and injuries are at issue in each case, Bendectin cases nationwide "are variations on a theme, somewhat like an orchestra which travels to different music halls, substituting musicians from time to time but playing essentially the same repertoire." (A3). Surveying recent caselaw, the court found massive inconsistency in the federal courts, and to a lesser extent in the state courts: some juries found particular injuries caused by Bendectin while others refused to so find; some trial courts ruled expert opinion admissible and sufficient while other courts ruled to the contrary on one or both issues; and appellate courts that had also gone both ways. (A3-A6).

As the Sixth Circuit analyzed the situation, this inconsistency was a problem that had to be solved, and one that originated

from a previous lack of judicial will:

> The fundamental reasons for the inconsistency of the legal system in handling Bendectin claims appear to be first, the difficulty of scientists and hence of judges, lawyers and jurors in knowing what reasonable inferences of causation to draw from animal experiments and epidemiological studies; and second, the uncertainty of judges about how far they should enter the scientific thicket of conflicting inferences in order to determine whether the basis of a scientific opinion concerning causation is sufficiently plausible to allow a jury to ground a verdict on it.

(A6).

Surveying the administrative law context in search of solutions, the Sixth Circuit concluded that the danger that different juries might reach inconsistent results on common issues of scientific fact requires judges to "apply a 'hard look' doctrine . . . in scientific cases based primarily on expert testimony," one that ensures "close judicial analysis of such technical and specialized matter." (A6-A7.) The Sixth Circuit justified this choice "not only because of the likelihood of juror misunderstanding, but also because expert witnesses are not necessarily always unbiased scientists," but "are paid by one side for their testimony," thus producing the "potential for exaggeration and fraud" that only a court could discern, through "close inspection and careful consideration of the record." (A6-A7). Only through this means, the Sixth Circuit concluded, could it guard against what it saw as "a 'combination of danger signals' requiring enhanced 'judicial vigilance to enforce the Rule of Law.'" (A7 (citation omitted)).

5. Applying this dual approach -- requiring judicial scrutiny of the weight of competing expert opinions on a Rule 56 summary judgment analysis, coupled with an especially intense "hard look" review to prevent undue inconsistency in jury verdicts -- the Sixth Circuit then rendered a decision on the facts of this case.

On the one hand, after an exhaustive, detailed review of the epidemiological studies relied on by Merrell's experts, *see* A8-A14, the Sixth Circuit agreed with criticisms of these studies put

forth by the Turpins' experts. (*See* A14-A16). Although these studies "constitute[d] evidence on which a jury might ground a defendant's verdict," they were "by no means conclusive." Merrell's experts had "overstate[d] the persuasive power of these statistical studies." (A16). The current science of epidemiology, the court ruled, could not eliminate "significant scientific uncertainty" about the value of the studies. (A16).

The Sixth Circuit then moved onto an equally exhaustive analysis of the persuasiveness those elements of Turpin expert affidavits relying on animal studies. (*See* A16-A20). Here the Sixth Circuit found what it regarded as "[t]he weakness of the plaintiffs' case." (A19). The problem was simple: "This weakness arises from the fact that different species of animals react differently to the same stimuli for reasons not entirely understood," so that it might not be reasonable in a particular case for "a reasonable jury to find that it is more probable than not that the substance causes a similar harm to humans." (A19-A20). Because Dr. Palmer, along with some of Merrell's experts, had relied on animal studies in forming their opinions on causation, the Sixth Circuit could not find "that this testimony is anything more than a personal belief or opinion," although it did not explain what it meant by this statement." (A21). In Dr. Palmer's succinct affidavit submitted only for summary judgment purposes to demonstrate the existence of an issue of fact and not to prove that fact in detail, the court could not find an "understandable scientific basis." (A21). Dr. Palmer's conclusion, the court found, went "far beyond the known facts" and was "overstate[d]." While recognizing that "[a]nimal studies often comprise the backbone of evidence indicating biological hazards, and their legal value has been recognized by federal courts and agencies," (A21), on a record of this nature the Sixth Circuit insisted that the "analytical gap" was simply "too wide," and upheld the grant of summary judgment to ensure that inconsistent jury verdicts could not result. (A22).

REASONS FOR GRANTING THE WRIT

1. This Court Should Resolve the Circuit Conflict Over Whether Federal Courts May Grant Summary Judgment On Contested Factual Issues by Weighing the Relative Credibility of the Opinions of Competing Qualified Experts

In its holding that on a summary judgment ruling "a court should judge for itself the validity of the reasoning process by which various competing qualified experts have reached their conclusions," rather than "leav[ing] that question for the jury," (A1), the Sixth Circuit joined a substantial conflict in the circuits over whether this type of close judicial scrutiny of expert opinion testimony is permissible under Fed. R. Civ. P. 56(e).

The conflict is the product of tension between two provisions: Rule 56(e) promulgated by this Court in 1963, which requires summary judgment affidavits to "set forth specific facts," and Fed. R. Evid. 705, enacted by Congress in 1975, which states that an expert may render his opinion "and give his reasons therefore *without* prior disclosure of the underlying facts or data" (emphasis added). This issue is important to all types of expert opinion testimony, not just to testimony concerning scientific issues, and fully warrants this Court's plenary review.

The second-to-last sentence of Fed. R. Civ. P. 56(e) requires that when a party answering a summary judgment submits affidavits or other materials, these materials "must set forth specific facts showing that there is a genuine issue for trial." This requirement was added through the 1963 amendment of Rule 56(e), "to disapprove a line of cases allowing a party opposing summary judgment to resist a properly made motion by reference only to its pleadings." *Celotex Corp. v. Catrett*, 477 U.S. 317, 325 (1986). Under it, the nonmoving party may oppose using "any of the kinds of evidentiary materials listed in Rule 56(c), except the mere pleadings themselves." *Id.* at 324.

Despite its original limited aim, during the past decade this new requirement of Rule 56(e) has been employed by several circuits as an all-purpose tool for judging the credibility of expert opinions on particular factual issues. Even though these opinions are rendered by qualified experts and in admissible form and thus

may be believed by a jury, several circuits have assumed unbridled discretion under Rule 56(e) to grant summary judgment where they believe that the *reasoning* and *information* cited in support of the expert's ultimate opinion does not include enough "specific facts."

The earliest circuit unambiguously to adopt this approach was the Ninth Circuit. In *United States v. Various Slot Machines on Guam*, 658 F.2d 697 (9th Cir. 1981), the court noted that Rules 704 and 705 of the Federal Rules of Evidence explicitly permit an expert to present an opinion that "embraces an ultimate issue to be decided," and to do so "without prior disclosure of the underlying facts or data, unless the court requires otherwise." *Id.* at 700. "[I]t can be argued," the Ninth Circuit explained, "that an expert's conclusion or opinion meets the requirement of Rule 56(e) that the party opposing the motion 'must set forth specific facts showing that there is a genuine issue for trial.'" *Ibid.* But the Ninth Circuit rejected this straightforward reading of the relevant language, stating that it had "difficulty with the notion that to state an opinion is to set forth specific facts," and it held that "in the context of a motion for summary judgment, an expert must back up his opinion with specific facts." *Ibid.*

The Ninth Circuit was followed by the Eleventh Circuit in *Evers v. General Motors Corp.*, 770 F.2d 984 (11th Cir. 1985). In *Evers*, a highly qualified automobile engineer stated by affidavit that he was thoroughly familiar with various categories of facts concerning a particular car accident, and he gave an ultimate opinion that provision of an airbag in the car would have minimized injuries to the occupants. With much of the same tone as the Sixth Circuit opinion in the instant case, the Eleventh Circuit granted summary judgment to the defendant, complaining that the affidavit, "though it purports to be based upon a review of the evidence, fails to provide *specific* facts to back up its conclusory allegations" -- that is, it did not explain in detail *why* and *how* the expert had reached his conclusion. *Id.* at 986-87 (emphasis added). The court specifically rejected the claim that enactment of Rule 705 "alter[ed] the requirement of [Rule] 56(e) that an affidavit must set forth specific facts in order to have any probative value." *Ibid.*

The Seventh Circuit has also recently used Rule 56(e) to abort the trial of factual issues even where admissible expert opinions have been offered, if the court finds these opinions lacking in specifics and therefore in perceived utility. For example, in *Mid-State Fertilizer Co. v. Exchange National Bank*, 877 F.2d 1333 (7th Cir. 1989), a highly qualified banking expert stated several ultimate opinions on a banking arrangement; his opinions were in admissible form and described generally the information on which they were based. The Seventh Circuit upheld the district court's finding that the affidavit was insufficient, stating that, although "Rule 705 of the Federal Rules of Evidence allows experts to present naked opinions," "[a]dmissibility does not imply utility," the court complained that the expert "presented nothing but conclusions -- no facts, no hint of an inferential process, no discussion of hypotheses considered and rejected." *Id.* at 1339. The court observed that "[a]n expert who supplies nothing but a bottom line supplies nothing of value to the judicial process." *Ibid.* The court bluntly warned that "[j]udges should not be buffaloed by unreasoned expert opinions" and that "'[t]he importance of safeguarding the integrity of the [judicial] process requires the trial [or appellate] judge, when he believes that an expert's testimony has fallen below professional standards, to say so, as many judges have done.'" *Id.* at 1340 (citation omitted). *See also Kenosha Liquor Co. v. Heublein, Inc.*, 895 F.2d 418, 420 (7th Cir. 1990) (holding: "Expert opinions are worthless without data and reasons. Kenosha Liquor has a worthless opinion, and Heublein is entitled to judgment.").

The reasoning of the contrary line of cases is most succinctly summed up by a sentence in the recent Tenth Circuit opinion in *Quinton v. Farmland Industries, Inc.*, 928 F.2d 335 (10th Cir. 1991). Stating that a challenge to sufficiency of evidence on a factual issue must fail if there is admissible expert opinion testimony on the issue, the court stated: "It is a truism that 'an expert's opinion or interpretation of evidence is itself evidence.'" *Id.* at 338 (quoting *Rodriguez v. Olin Corp.*, 780 F.2d 491, 496 (5th Cir. 1986)). In other words, the opinion, if believed by the

jury, establishes a fact and thereby itself can suffice to meet the requirement of Rule 56(e) that "specific facts" be set forth. As several circuits have recognized, this conclusion logically flows from the language of the expert testimony rules of the Federal Rules of Evidence, Congress's purpose in enacting them, and the constraint of the Seventh Amendment.

The opinions of the D.C. Circuit are especially clear. The most important principle is that under the expert testimony rules as structured by Congress, when an expert *does* elect in an affidavit to provide exhaustive detail about the data and reasoning forming the basis of his opinion -- as did the Turpins' experts in this case -- this detail is *not* something that thereby goes into evidence, becomes accessible to weighing and scrutiny by *the court*, and thus might warrant a grant of summary judgment for insufficiency. Instead, when an expert provides such detail he does so by virtue of Rule 703, which overrides for experts the "prohibition against hearsay evidence" and "permits an expert witness to base his opinion on facts or data which would not be admissible as competent evidence so long as the facts or data are of a type reasonably relied on by experts in the particular field." *United States v. Wright*, 783 F.2d 1091, 1100 (D.C. Cir. 1986). *See also* p. 3 & n.1, *supra*. The only purpose of such detail is to bolster the *credibility* of the expert. "Read together, Rules 703 and 705 reveal that the data underlying an expert's opinion which is elicited on cross-examination does not come in as substantive evidence," and only "is admitted for the limited and independent purpose of enabling the jury to scrutinize the expert's reasoning." *Ibid.* Under the structure established by Congress, a court has no business looking to this underlying detail on its own in order to find the expert not credible.

The Fourth Circuit echoed this construction of Rules 703 and 705 in its recent decision in *United States v. A & S Council Oil Co.*, 947 F.2d 1128 (4th Cir. 1991). The court recognized that under the expert testimony rules an expert witness is permitted to introduce into evidence general opinions concerning a given factual issue, and that such generality without a check of some sort could be dangerous. But Congress structured the Rules to ensure that a vigorous adversarial process would be available to

cure potential abuses:

> Full examination of the underpinnings of an expert's opinion is permitted because the expert, like all witnesses, puts his credibility in issue by taking the stand.
>
> * * *
>
> . . . Rule 703 creates a shield by which a party may enjoy the benefit of inadmissible evidence by wrapping it in an expert's opinion; Rule 705 is the cross-examiner's sword, and, within very broad limits, he may wield it as he likes.

Id. at 1135. *See also Smith v. Ford Motor Co.*, 626 F.2d 784, 793 (10th Cir. 1980) ("[t]he combined effect of these new rules [Rules 703 and 705] is to 'place the full burden of exploration of the facts and assumptions underlying the testimony of an expert witness squarely on the shoulders of opposing counsel's cross-examination'") (citations omitted); *DeLuca v. Merrell Dow Pharmaceuticals, Inc.*, 911 F.2d 941, 956 (3d Cir. 1990) (the Rules "embody a strong and undeniable preference for admitting any evidence having some potential for assisting the trier of fact and for dealing with the risk of error through the adversary process") (citing *Barefoot v. Estelle*, 463 U.S. 880, 899 & 901 n.7 (1983)).

As the D.C. Circuit held in a decision involving causation issues in a landmark toxic tort case, when qualified experts testify to different conclusions about causation relying on similar sources of data and "differ[] solely on the conclusions they [draw] from the test results and other information," this is a "classic battle of the experts . . . in which the jury must decide the victor." *Ferebee v. Chevron Chemical Co.*, 736 F.2d 1529, 1535 (D.C. Cir.), *cert. denied*, 469 U.S. 1062 (1984) (citation omitted). As to the claim that the defendant's claim of non-causation was so strong that the jury should not be allowed to disbelieve it, the *Ferebee* court remarked that "[t]he short answer to [defendant's causation] argument is that two expert witnesses refuted it and that the jury was entitled to believe those experts." *Ibid.*

The D.C. Circuit's *Ferebee* holding is consistent with this Court's approach to credibility issues generally and to expert witness credibility in particular. This Court has explained that,

under Rule 56(e), a "dispute about a material fact is 'genuine' . . . if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). As this Court observed in *Anderson*, "it is clear enough from . . . recent cases that at the summary judgment stage the judge's function is not himself to weigh the evidence and determine the truth of the matter but to determine whether there is a genuine issue for trial." *Id.* at 249. Most fundamentally, this Court has emphasized, the role of the jury may not be denigrated through use of such a trial by affidavit, because "[c]redibility determinations, the weighing of the evidence, and the drawing of legitimate inference from the facts are jury functions." *Id.* at 255. It is the very "'purpose of the jury . . . to sort out the true testimony from the false, the important matters from the unimportant matters, and, when called upon to do so, to give greater credence to one party's expert witnesses than another's. Such matters occur routinely in the American judicial system, both civil and criminal.'" *Barefoot v. Estelle*, 463 U.S. 880, 902 (1983) (citation omitted).

The distortion of Rule 56(e) by several circuits to authorize judges to perform such forbidden functions and judge expert witness credibility is in plain conflict with the Seventh Amendment, because it has no conceivable analogue in procedural law circa 1791. *See Parklane Hosiery Co. v. Shore*, 439 U.S. 322, 336-37 (1979). The Seventh Amendment's history makes clear that its central mission is to prevent just such a takeover of jury functions and thus to check the power of autocratic, life-tenured federal judges by entrusting factual disputes to people *other* than the sovereign's judges, however inefficient this can at times be. *See id.* at 337-56 (Rehnquist, J., dissenting); *see also Granfinanciera, S.A. v. Nordberg*, 492 U.S. 33, 83 (1989) (White, J., dissenting) ("'The function of the civil jury is to diffuse the otherwise autocratic power and authority of the judge.'"). The square holding of the court below that a court may "judge for itself the validity of the reasoning process by which various competing qualified experts have reached their conclusions" rather than "leav[ing] that question for the jury" (A1) is indefensible. The plenary attention of this Court over the

Rule 56(e) circuit conflict and over such casual disrespect for the Seventh Amendment is necessary.

2. This Court Should Decide Whether Federal Courts Possess Inherent Judicial Power to Battle "Inconsistent" Jury Verdicts by Imposing Nationwide Uniformity on Scientific Issues Common to Diversity Cases Arising Under the Law of the 50 States

This case provides this Court with an opportunity to speak with a clear voice about the limits of inherent judicial power, a subject which engendered a 5-to-4 split in *Chambers v. NASCO, Inc.*, 111 S. Ct. 2123 (1991). The majority in *Chambers* ruled that the federal courts' inherent powers to impose sanctions for bad-faith conduct had not been displaced by the scheme of statutes and rules available to target such conduct, *see id.* at 2131-36, and the sanctions imposed in that particular diversity case did not run afoul of the *Erie* doctrine because they did not have substantive effects. *See id.* at 2136-38.

Justice Kennedy, in dissent, argued that the decision "effects a vast expansion of the power of federal courts, unauthorized by rule or statute." *Id.* at 2141 (Kennedy, J., joined by Rehnquist, C.J. and Souter, J., dissenting). In the view of Justice Kennedy, the majority was "allowing courts to ignore express Rules and statutes on point" and was defying the precept that "[i]nherent powers are the exception, not the rule, and their assertion requires special justification in each case." *Id.* at 2143. By authorizing imposition of sanctions for prelitigation primary conduct, Justice Kennedy argued, "[t]he inherent power exercised here violates the fundamental tenet of federalism announced in *Erie* by regulating primary behavior that the Constitution leaves to the exclusive province of States." *Id.* at 2148. Justice Scalia also voiced serious concerns. *Id.* at 2140-41 (Scalia, J., dissenting).

The Sixth Circuit's bold construction of an *ad hoc* mechanism with which to solve the supposed problem of "inconsistent results reached by courts and juries nationwide on

the question of causation in Bendectin birth defects cases" (A1) demonstrates a fundamental lack of respect for the limits on judicial power, and for the real constraints on federal judicial discretion imposed by the *Erie* doctrine. Both the majority and dissenting Justices in *Chambers* should be able to agree that the decision below is a fundamental abuse of judicial power that at minimum should be subject to the exercise of this Court's supervisory power. This case presents an important opportunity for this Court to underscore to the lower federal courts basic axioms regarding the proper judicial role under Art. III.

Perhaps the most illegitimate feature of the decision below lies in its strange assumption that different jury verdicts in cases involving different Bendectin plaintiffs is a "problem" in demand of a judicial "solution" -- here a solution that applies the administrative law "hard look" doctrine to civil diversity cases out of a fear that juries cannot be trusted to perceive the "danger signals" that sometimes accompany expert testimony.

In fact, this pattern of so-called "inconsistency" is simply an endemic feature of a case-by-case system of adjudication coupled with the use of a lay jury as a means of providing a needed check on the power of the life-tenured Judiciary. As Justice Kennedy observed in the far more visible and troublesome area of inconsistent punitive damage awards, the evolution of the jury system over the centuries in general demonstrates that "[o]ur legal tradition is one of progress from fiat to rationality," and "[e]lements of whim and caprice do not predominate" in a properly functioning jury system. *Pacific Mutual Life Ins. Co. v. Haslip*, 111 S. Ct. 1032, 1055 (1991) (Kennedy, J., concurring in the judgment). "Some inconsistency of jury results can be expected," of course, partly because "the jury is empaneled to act as a decisionmaker in a single case, not as a more permanent body. As a necessary consequence of their case-by-case existence, juries may tend to reach disparate outcomes based on the same instructions." *Ibid.*

Indeed, in the area of *criminal* law -- even in the *same* case -- "[i]t has, of course, long been the rule that consistency in verdicts or judgments of conviction is not required." *Hamling v. United States*, 418 U.S. 87, 100 (1974). In fact, "'it is common

experience that different juries may reach different results under any criminal statute. That is one of the consequences we accept under our jury system.'" *Ibid.* (citation omitted).

Although an argument might be made that the Sixth Circuit's "solution" to the problem of inconsistency -- to override the policy choice made by Congress in enacting the Federal Rules of Evidence, of entrusting the weight of expert testimony to juries -- is from some perspective more efficient or rational than the current system, that calculus is irrelevant. As Chief Justice Rehnquist stated some time ago, any such sentiment "cannot obscure or dilute [the] obligation to enforce the Seventh Amendment, which *was* included in the Bill of Rights in 1791," based on the view that civil jury trials are "an important bulwark against tyranny and corruption," not on the view "that use of juries would lead to more efficient judicial administration." *Parklane Hosiery Co. v. Shore*, 439 U.S. 322, 338, 343 (1979) (Rehnquist, J., dissenting) (emphasis in original). In sum, "no amount of argument that [a new procedural] device provides for more efficiency or more accuracy or is fairer will save it if the degree of invasion of the jury's province is greater than allowed in 1791." *Id.* at 346 .

This fundamental principle was lost on the Sixth Circuit as it reinvented the civil justice system to take decision of close scientific issues in commonly litigated cases away from the jury, based on an analysis of the credibility of competing experts. The Sixth Circuit is not the first to lose its way. In *Brock v. Merrell Dow Pharmaceuticals, Inc.*, 874 F.2d 307, *modified*, 884 F.2d 166, *reh'g denied*, 884 F.2d 167 (5th Cir. 1989), *cert. denied*, 110 S. Ct. 1511 (1990), the Fifth Circuit confronted the problem of inconsistent Bendectin verdicts with a solution even more excessive of the Judicial power and invasive of the jury system. "Mass tort" cases, the Fifth Circuit wrote, "present special problems and challenges to traditional ideas regarding the role of the jury as a decisionmaker." *Id.* at 309. The problem with Bendectin and other similar cases, it announced, is that "there is often no consensus in the medical community about whether a given substance" causes birth defects, and therefore "juries often split both ways the issue," thus creating in drug manufacturers

"uncertainty which can tend to produce a sub-optimal amount of new drug development." *Id.* at 309-10. The solution imposed by the Fifth Circuit was much like that imposed by the Sixth Circuit: *regardless* of the content of governing rules of evidence and procedure, for this class of cases "courts must critically evaluate the reasoning process by which the experts connect data to their conclusions in order for courts to *consistently* and *rationally* resolve the disputes before them." *Id.* at 310 (emphasis added). To achieve consistency and rationality, the Fifth Circuit ruled that unless and until a Bendectin plaintiff could produce an epidemiological study exhibiting "statistical significance" -- that is, suggesting a link between Bendectin and birth defects with 95% confidence -- no plaintiff could recover anywhere in the Fifth Circuit. *Id.* at 311-15.

A number of lower federal court judges have, of course, rebelled from cases like *Brock*, the Sixth Circuit decision below, and similar attempts to reinvent the civil justice system, revealing a conflict in the circuits providing rich material for this Court's consideration of the fundamental issues involved here. For example, in *Brock* itself six judges, including Judge Patrick Higginbotham, dissented from denial of rehearing *en banc*; among other things they were puzzled over "what is left in this circuit of . . . the Seventh Amendment right to trial by jury." 844 F.2d at 168.

In *DeLuca v. Merrell Dow Pharmaceuticals, Inc.*, 911 F.2d 941 (3d Cir. 1990), also a Bendectin case, the court stated that it understood and sympathized "with the concerns expressed in *Brock* over the costs and inequities that flow from inconsistent outcomes in Bendectin cases, the potential effect erroneous verdicts have on the availability of useful medicines, and the wastefulness of continued reconsideration of an identical scientific issue in the courts." *Id.* at 951-52. However, the Third Circuit clearly recognized that it could not attempt to solve these policy problems through exercise of its inherent judicial power or through manipulation of the rules laid down by Congress and by this Court:

> . . . [W]e do not have authority to create special rules to address the problems posed by continued Bendectin

> litigation. Principles of issue preclusion have not developed to the point where we may bind plaintiffs by the finding of previous proceedings where they are not parties . . . . Nor are we at liberty, especially in a case to be decided under our diversity jurisdiction, to impose different burdens of proof on Bendectin plaintiffs than those that would apply in analogous products liability suits.

Id. at 952.

Finally, Judge Patrick Higginbotham, writing for the Fifth Circuit, honored the limits on the role defined for the courts in the context of the far more burdensome asbestos litigation, in *In re Fibreboard Corp.*, 893 F.2d 706 (5th Cir. 1990). He rejected a district court's attempt to impose on defendants a quasi-administrative dispute-resolution scheme that extrapolated from the average results of early "test" cases and which would have denied the defendants their Seventh Amendment and due process rights in thousands of cases, thereby warping the applicable state tort law policy choices in violation of the *Erie* doctrine. In answer to the district court's plea that this innovative scheme was essential to solving a crisis facing the courts, Judge Higginbotham suggested that the representative branches be consulted and stated: "The Judicial Branch can offer the trial of lawsuits. It has no power or competence to do more." *Id.* at 712.

The willingness of the Sixth Circuit below, like that of the Fifth Circuit in *Brock*, to employ inherent judicial power in the exercise of its *diversity jurisdiction* to force a consistent result in Bendectin cases with no regard for the underlying state law is a shocking violation of this Court's *Erie* jurisprudence. Both the Sixth Circuit's rule that epidemiological studies are not especially probative, combined with its requirement that to pass the summary judgment stage a Bendectin plaintiff must come up with an especially cogent and thorough analysis of available animal studies; and the Fifth Circuit's completely opposite rule that a Bendectin plaintiff must come up with "statistically significant" epidemiological studies, because animal studies are almost worthless, obviously have *no relation at all* to the substantive law of the several States covered within each circuit. The effect

of these rules is to create special presumptions or burdens of proof barring a finding of liability until a unique quantum of proof can be mustered by a plaintiff -- rules that are clearly "substantive" within the meaning of the *Erie* doctrine. *See, e.g.*, *Dick v. New York Life Ins. Co.*, 359 U.S. 437, 446-47 (1959); *Cities Service Oil Co. v. Dunlap*, 308 U.S. 208 (1939).[4]

These special Fifth and Sixth Circuit rules approaches to certain kinds of tort cases trigger the gravest concerns underlying the *Erie* doctrine because they impact on prelitigation conduct (Merrell faces a reduced threat of liability for marketing Bendectin to the extent that many claims can be removed to federal court) and because differences in the rules applied in federal and state courts clearly encourage forum shopping by both plaintiff and defendant. *See, e.g.*, *Chambers*, *supra*, 111 S. Ct. at 2148-49 (Kennedy, J., joined by Rehnquist, C.J. and Souter, J., dissenting). In the short time since the Sixth Circuit handed down the decision below, the courts of a State within the Sixth Circuit region have ruled that a Bendectin case could go forward over a sufficiency-of-evidence objection by Merrell (*see* Appendix C, at A37), and a trial court within a State within the Fifth Circuit region entered judgment against Merrell in another Bendectin case (*see* Appendix D, at A41).

Because state courts remain open to many Bendectin plaintiffs, as long as courts like the Fifth and Sixth Circuits persist in adhering to *ad hoc* doctrines to rid their dockets of such cases, and as long as the lessons of *Erie* remain lost on such courts, the differences between the results reached in federal and state courts will increase and the quest for consistency of adjudication will ironically become ever more quixotic. Only prompt intervention by this Court can ensure that procedural regularity and fundamental constitutional values will prevail over growing judicial anarchy in the lower federal courts.

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[4] Kentucky substantive tort law, which controls this case, employs no such special presumptions or burdens. *See, e.g.*, *Steelvest, Inc. v. Scansteel Service Center, Inc.*, 807 S.W. 2d 476, 481-83 (Ky. 1991); *Rogers v. Kasdan*, 612 S.W.2d 133, 134-35 (Ky. 1981); *Kentucky Power Co. v. Halcomb*, 373 S.W.2d 725 (Ky. App. 1963).

CONCLUSION

For all these reasons, certiorari should be granted.

Respectfully submitted,

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June 9, 1992

APPENDICES

APPENDIX A

Decision of the United States Court of Appeals for the Sixth Circuit, affirming the district court's grant of summary judgment for respondent, dated March 11, 1992 . . . . . A1

APPENDIX B

Memorandum and Order of the United States District Court for the Eastern District of Kentucky, granting summary judgment for respondent, dated April 25, 1989 . . . . . A23

APPENDIX C

Order of the Michigan Supreme Court in *DePyper v. Navarro*, dated April 21, 1992, and of the Michigan Court of Appeals, dated May 9, 1991 . . . . . A37

APPENDIX D

Final Judgment in the District Court of Nueces County, Texas, finding for plaintiffs in *Havner v. Merrell Dow*, dated June 1, 1992 . . . . . A41

APPENDIX A

GARY TURPIN, *Plaintiff-Appellant*, BETTY TURPIN, Individually and as Parent and Natural Guardian of Brandy Turpin, a Minor, *Plaintiff*, v. MERRELL DOW PHARMACEUTICALS, INC., *Defendant-Appellee*.

No. 90-5690

UNITED STATES COURT OF APPEALS
For The Sixth Circuit

March 11, 1992, Decided and Filed

Before: MERRITT, Chief Judge; KENNEDY and JONES, Circuit Judges:

MERRITT, Chief Judge. For a judicial system founded on the premise that justice and consistency are related ideas, the inconsistent results reached by courts and juries nationwide on the question of causation in Bendectin birth defect cases are of serious concern. In this Bendectin causation case, Judge Eugene Siler concluded that the evidence adduced on summary judgment was insufficient to allow a rational jury to find that Bendectin, a drug given to pregnant women to counteract the nausea of "morning sickness," caused the minor plaintiff's birth defects.

The general issue for review here is whether the trial judge erred by withdrawing the case from the jury and by granting summary judgment for the defendant pharmaceutical company. The more specific issues are, first, whether a court should judge for itself the validity of the reasoning process by which various competing qualified experts have reached their conclusions or should instead leave that question for the jury; and second, whether the evidence in this case, if so reviewed, is sufficient to withstand the defendant's motion for summary judgment.

We agree with Judge Siler that, although judges should respect scientific opinion and recognize their own limited scientific knowledge, nevertheless courts have a duty to inspect

the reasoning of qualified scientific experts to determine whether a case should go to the jury. Based on the record before us, we also agree with Judge Siler that whether Bendectin caused the minor plaintiff's birth defects is not known and is not capable of being proved to the requisite degree of legal probability based on the scientific evidence currently available. Taken in the light most favorable to the plaintiffs, the scientific evidence that provides the foundation for the expert opinion on causation in this case is not sufficient to allow a jury to find that it is more probable than not that Bendectin caused the minor plaintiff's injury. Therefore the case should not go to a jury.

We will first summarize the Bendectin causation issue and the case law that has developed during the past twelve years. We will then analyze the evidence in greater detail and show why it does not meet the legal test of causation.

I. *Overview*

The nausea of morning sickness affects many pregnant women and, although the causes are not completely understood, in extreme cases may cause permanent injury to the sufferer's unborn child. Merrell Dow manufactured and marketed Bendectin as an anti-nauseant prescription for morning sickness from 1956 until 1983 when it took the drug off the market despite continued approval from the Food and Drug Administration. Estimates indicate that Bendectin was prescribed from 1957 until 1982 to over 30 million women worldwide and to more than 17.5 million women in the United States. These women commonly took Bendectin during the first trimester of pregnancy.

Approximately seven weeks after becoming pregnant, Betty Turpin ingested Bendectin to combat morning sickness. The initial development of the fetus's fingers and toes occurs some four to eight weeks after conception. Seven months after Ms. Turpin first took the drug, her child, Brandy Turpin, the infant plaintiff in this case, was born with "limb reduction defects": severely deformed hands and feet, specifically fused joints and shortened or missing fingers and toes. Ms. Turpin took no other drugs during the course of her pregnancy, nor can her child's deformities be traced to any known genetic disorders.

Causation here is a matter of trying to measure probabilities. It requires a complex series of inferences drawn from scientific experiment and observation and statistical comparisons. For example, the plaintiffs rely primarily on animal experiments from which an inference is drawn that since chemical compounds in Bendectin, if administered at certain levels, cause birth defects in animals, they may cause similar defects in humans. The plaintiffs draw a further inference that Bendectin caused the birth defects in this particular case. These inferences are necessary because physicians who treated Brandy Turpin and other similarly situated children cannot diagnose the cause of these anomalies.

The defendant, too, reasons from the results of scientific studies to a particularized conclusion with respect to these plaintiffs. Merrell Dow relies primarily on statistical studies that purport to show that the incidence of certain birth defects is no higher with women who used Bendectin than with those who did not or, in the alternative, that where statistical associations indicating a possible causal relationship exist, they would not lead a reasonable expert to infer that Bendectin causes birth defects.

The causation proof in Bendectin birth defect cases is offered by expert witnesses who speak in terms of population groups and statistical samples rather than specific individuals. The expert witnesses on each side are often the same, from case to case, and even when different the scientific conclusions and theories are based on the same or similar statistical studies and scientific experiments. The cases are variations on a theme, somewhat like an orchestra which travels to different music halls, substituting musicians from time to time but playing essentially the same repertoire.

A brief survey of the reported Bendectin cases illustrates the inconsistency of courts that have dealt with the scientific problem of causation. We find only one reported case finally upholding a finding of causation. In *Oxendine v. Merrell Dow Pharmaceuticals, Inc.*, 506 A.2d 1100 (D.C. App. 1980), *aff'd in part on appeal after remand*, 563 A.2d 330 (D.C. App. 1989), *cert. denied*, 493 U.S. 1074 (1990), the appellate court reversed the

trial court's grant of a judgment n.o.v. and motion for new trial to the defendant and reinstated the jury's $750,000 verdict for the plaintiffs. On the other hand, in four other reported cases, juries returned verdicts for the defense which were allowed to stand. *Wilson v. Merrell Dow Pharmaceuticals*, 893 F.2d 1149 (10th Cir. 1990) (affirming judgment for the defendant and noting also that the plaintiffs' motion for judgment n.o.v. was correctly denied by the district judge); *Will v. Richardson--Merrell, Inc.*, 647 F. Supp. 544 (S.D. Ga. 1986) (denying plaintiffs' motion for judgment n.o.v.); *In re Richardson-Merrell, Inc. "Bendectin" Products Liability Litigation*, 624 F. Supp. 1212 (S.D. Ohio 1985), *aff'd*, 857 F.2d 290 (6th Cir. 1988) (denying plaintiffs' motion for judgment n.o.v. in an order addressing 818 of 844 consolidated multidistrict cases in the largest of all Bendectin cases); and *Cosgrove v. Merrell Dow Pharmaceuticals, Inc.*, 117 Idaho 470, 788 P.2d 1293 (1990) (affirming jury's finding that Bendectin was not the proximate cause of child's injuries).

Four federal circuits have held that plaintiffs failed as a matter of law to establish causation of birth defects. The Fifth Circuit, without ruling specifically on the admissibility of the plaintiffs' expert testimony, reversed a jury verdict for the plaintiffs and granted judgment n.o.v. to the defendant because adequate proof of causation was lacking. *Brock v. Merrell Dow Pharmaceuticals, Inc.*, 874 F.2d 307, *reh'g. denied*, 884 F.2d 166 (5th Cir. 1989), *cert. denied*, 110 S. Ct. 1511 (1990), *limited by Christopherson v. Allied-Signal Corp.*, 902 F.2d 362, 367 (5th Cir. 1990), *rev'd on reh'g on other grounds*, 939 F.2d 1106 (5th Cir. 1991)(en banc). Another circuit, the Ninth, affirmed a grant of summary judgment for the defendant after holding that the plaintiffs' reanalyses of Merrell Dow's epidemiological studies were unreliable for lack of peer review. *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, No. 90-55397, 1991 U.S. App. LEXIS 29497 (9th Cir. Dec. 20, 1991). Two other circuits reached the same result by ruling inadmissible the plaintiffs' expert testimony on grounds that it was not the type "reasonably relied upon" by qualified experts in the specific fields of study. *Richardson v. Richardson-Merrell, Inc.*, 857 F.2d 823 (D.C. Cir. 1988), *cert. denied*, 493 U.S. 882 (1989) (reversing jury

verdict for the plaintiff; in the face of the defendant's epidemiological evidence, an insufficient foundation existed for the plaintiffs' animal and chemical studies); *Lynch v. Merrell-Nat'l Labs.*, 830 F.2d 1190 (1st Cir. 1987) (holding that the plaintiff's *in vivo* and *in vitro* studies were inadmissible; therefore, insufficient evidence existed to avoid summary judgment for the defendant); *see also Ealy v. Richardson-Merrell, Inc.*, 897 F.2d 1159 (D.C. Cir.), *cert. denied*, 111 S. Ct. 370 (1990) (reversing jury verdict for the plaintiff for $20 million in compensatory damages and punitive damages of $75 million, and granting judgment n.o.v. to the defendant after concluding that the plaintiff's evidence was inadmissible under *Richardson*), and *Ambrosini v. Richardson-Merrell, Inc.*, No. 86-278 (D.D.C. June 30, 1989)(relying on *Richardson* in granting judgment for the defendants).

Four District Court cases nationwide have granted summary judgment to the defendant for various reasons. *Lee v. Richardson-Merrell, Inc.*, No. 84-2228 (W.D. Tenn. Jan. 30, 1991) (relying on *Richardson*, *Brock*, and Judge Siler's opinion in this case); *Cadarian v. Merrell Dow Pharmaceuticals, Inc.*, 745 F. Supp. 409 (E.D. Mich. 1989) (holding that an inadequate foundation existed for expert's s opinion); *Hull v. Merrell Dow Pharmaceuticals, Inc.*, 700 F. Supp. 28 (S.D. Fla. 1988) (finding that the body of scientific literature established Bendectin's safety and that the infant plaintiff's mother took the drug too late in her pregnancy to affect the fetus); and *Monahan v. Merrell-Nat'l Labs.*, No. 83-3108-WD (D. Mass. Dec. 18, 1987)(finding that summary judgment for the defendant was required under the First Circuit's earlier holding in *Lynch*).

In contrast, other courts have either denied or reversed on appeal grants of summary judgment for the defendant in eight cases. In *DeLuca v. Merrell Dow Pharmaceuticals, Inc.*, 911 F.2d 941 (3rd Cir. 1990), the Third Circuit reversed the trial court's grant of summary judgment to Merrell Dow and remanded for the District Court to analyze the reasonableness of an expert witness's epidemiological opinion of causation under Federal Rule of Evidence 702. *See also Longmore v. Merrell Dow Pharmaceuticals, Inc.*, 737 F. Supp. 1117 (D. Idaho 1990)

(expressly declining to adopt *Richardson*, *Lynch*, and *Brock* approaches); *In re Bendectin Products Liability Litigation*, 732 F. Supp. 744 (E.D. Mich. 1990) (holding that collateral estoppel did not bar the plaintiffs on the issue of causation and that, in the face of experts' disagreements on necessity of epidemiological proof, the court could not reject other types of evidence); and *DePyper v. Navarro*, No. 116390 (Mich. Ct. App. May 9, 1991) (holding that the trial court erred under state law by not inquiring whether experts in field generally accepted the methodology of the plaintiffs' expert). For other denials of summary judgment or denials of the defendant's motions for directed verdict, see *Hagen v. Richardson-Merrell, Inc.*, 697 F. Supp. 334 (N.D. Ill. 1988) (denying summary judgment on causation but granting summary judgment on punitive damages); *Mangels v. Richardson-Merrell, Inc.*, No. R-83-3272 (D. Md. Aug. 17, 1987) (summary judgment denied because a triable issue of fact existed for jury resolution); and *Lanzilotti v. Merrell Dow Pharmaceuticals, Inc.*, No. 82--0183 (E.D. Pa. July 10, 1086) (denying the defendant's motion for a directed verdict).

The fundamental reasons for the inconsistency of the legal system in handling Bendectin claims appear to be first, the difficulty of scientists and hence of judges, lawyers and jurors in knowing what reasonable inferences of causation to draw from animal experiments and epidemiological studies; and second, the uncertainty of judges about how far they should enter the scientific thicket of conflicting inferences in order to determine whether the basis of a scientific opinion concerning causation is sufficiently plausible to allow a jury to ground a verdict on it. There are two important questions here: How hard should judges look at the reasonableness of scientific theories and inferences before they decide whether there is enough to the case for it to go to the jury? If we apply a "hard look" doctrine, as we are inclined to do in scientific cases based primarily on expert testimony, what exactly are the general scientific experiments and studies capable of showing about whether Bendectin causes birth defects in a particular case?

We believe that close judicial analysis of such technical and specialized matter is necessary not only because of the likelihood

of juror misunderstanding, but also because expert witnesses are not necessarily always unbiased scientists. They are paid by one side for their testimony. Although there is no suggestion of unethical scientific conduct in the present case, the potential for exaggeration and fraud on the court is present and may be impossible to discover without close inspection and careful consideration of the record. As Judge Leventhal observed in the context of administrative law, in some circumstances there exists a "combination of danger signals" requiring enhanced "judicial vigilance to enforce the Rule of Law." *Greater Boston Television Corp. v. F.C.C.*, 444 F. 2d 841, 851-52 (D.C. Cir. 1970). In such situations, "a court does not depart from its proper function when it undertakes a study of the record, hopefully perceptive, even as to evidence on technical and specialized matters . . . ." *Id.* at 850. We find that this case presents a scenario justifying the type of judicial review recommended by Judge Leventhal.

II.

In this legal context, we review the evidence and arguments offered by the parties on summary judgment. In determining and applying the correct standards of proof on summary judgment in scientific cases, we look to the rules of sufficiency of the evidence to decide whether juries should be allowed to hear the evidence as well as the rules of admissibility of expert testimony that shape the facts and opinions to be considered. This case, we believe, should be decided on the rules of the sufficiency of evidence of causation on summary judgment, as Judge Siler held below in the alternative.

In the instant case, the plaintiffs claim that their infant daughter's birth defects were caused by the mother's use of Bendectin during her pregnancy and specifically by one ingredient, doxylamine succinate. The plaintiffs' case relies on animal studies and attacks the defendant's epidemiological studies. The defendant's case relies on the epidemiological studies and attacks the animal studies.

The plaintiffs offered expert opinions from ten witnesses in eight scientific fields to assess whether Bendectin is "teratogenic," *i.e.*, capable of causing birth defects. These opinions

were based on *in vitro* and *in vivo* animal studies, and reassessment of the defendant's epidemiological studies derived from study of humans. In support of its motion for summary judgment, the defendant relies primarily on 35 human epidemiological studies supporting a finding that the use of Bendectin does not cause birth defects. Some of these studies were conducted by scientists under contract with the defendant. Others were independent.

A. *Defendant's Proof -- Epidemiological Studies*

Both sides appear to accept the fact that limb defects generally appear in less than one in 1,000 live births. The defendant's proof consists in large measure of the 35 extant studies published in medical and scientific journals on the statistical relationship between the use of Bendectin and the incidence of various forms of birth defects in babies, none of which conclude that a causal connection exists. For an extended explanation of the complex statistical methodology used in such epidemiology studies, including the use of such terms of art as the "null hypothesis," "significance testing," "P value," "relative risk" and "confidence interval," see Part 1.B of the Third Circuit's recent Bendectin opinion, *DeLuca v. Merrell Dow Pharmaceuticals, Inc.*, 911 F.2d 941, 945-49 (3rd Cir. 1990).[1]

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[1] Several statistical terms of art are essential to an understanding of the meaning of these epidemiological studies. The risk of injuries from a suspected cause is expressed as *relative risk*. To calculate relative risk, the number of occurrences of a given birth defect in an exposed group is divided by the number of occurrences in the control, or unaffected group. If the given defect occurs with equal frequency between the exposed and control groups, the relative risk would be 1.0. A relative risk of 1.0 is considered inconclusive, in that a researcher cannot state that a suspected agent does or does not cause a defect (i.e., the "null hypothesis" or "no association"). *See generally* Allen Mitchell *et al.*, *Adverse Drug Effects and Drug Surveillance, in Pediatric Pharmacology* 68-69 (Sumner Yaffe ed. 1980). A relative risk of less than 1.0 suggests that a suspected agent does not cause a birth defect. A relative risk greater than 1.0 suggests that the substance may cause a given birth defect.

To gauge the reliability and credibility of their reports when repeated

randomly, statisticians use a device known as the *confidence interval*. The confidence interval is not a "burden of proof" in the legal sense; rather, it is a common sense mechanism upon which statisticians rely to confirm their findings and to lend persuasive power within their profession. The confidence interval has two components: a percentage, and an interval or range. The *percentage* part is established by the statistician in advance of performing the studies. Frequently this percentage is set at 95 percent, although that value is somewhat arbitrary and 85 to 90 percent figures are also used. The *interval*, on the other hand, represents a range of possible values at high and low ends of a scale of relative risk. *See, e.g.*, Kenneth Rothman, *Modern Epidemiology* 119 (1986). At a 95 percent interval the true relative risk value will be between the high and low ends of the confidence interval 95 percent of the time. *See* Neil Cohen, *Confidence in Probability: Burdens of Persuasion in a World of Imperfect Knowledge*, 60 N.Y.U. L.Rev. 385, 398-400 (1985) [hereinafter *Confidence in Probability*], for example of confidence intervals and their use.

To better understand confidence intervals, it may be helpful to picture a line, marked at hundredths intervals and extending from zero to infinity. The marking at 1.0 represents a relative risk of 1.0, the "null value." If a confidence interval of "95 percent between 0.8 and 3.10" is cited, this means that random repetition of the study should produce, 95 percent of the time, a relative risk somewhere between 0.8 and 3.10. Because this confidence interval includes relative risk values both less than and exceeding 1.0, the null value, a researcher cannot state that the results are statistically significant. David Kaye, *Is Proof of Statistical Significance Relevant?*, 61 Wash. L.Rev. 1333, 1343-44 (1986), *cited in DeLuca v. Merrell Dow Pharmaceuticals, Inc.*, 911 F.2d 941, 948 (3rd Cir. 1990). For an example of such a study, see Jose Cordero *et al.*, *Is Bendectin a Teratogen?*, 245 JAMA 2307 (1981), cited *infra*. Similarly, it is possible that a range may be entirely below 1.0, meaning that the agent does not cause birth defects. If, however, the confidence interval spans a range entirely above 1.0 -- *e.g.*, from 1.75 to 10.75 -- then this interval would be statistically significant and would show a greater likelihood that the suspected agent did cause the studied defect. For an example of such an interval, see Brenda Eskenazi & Michael Bracken, *Bendectin (Debendox) As a Risk Factor for Pyloric Stenosis*, 144 Am.J.Obstetrics & Gynecology 919 (1982), cited *infra*.

The sample size for any study also has an effect, both on the confidence interval and the "power" of the study. *Power* is the study's probability of detecting a difference in outcomes between exposed and non-exposed groups. *See* Office of Technology Assessment, Report No.

The following examples illustrate the nature and findings of these 35 studies, with six studies representative of the group:

1. ***The San Francisco Study***: Two University of California researchers studied effects of six anti-nauseant drugs on 11,481 pregnancies in the San Francisco area over seven years. Bendectin was prescribed in only 628 of these cases. Birth defects were monitored at three ages: one month, one year, and five years (though limb defects in particular were not isolated and reported). The average rate of all types of birth defects for Bendectin cases at the age of one month was 0.8 in every 100 births. This average rate is less than the average rate of the birth defects found in mothers who did not use Bendectin. The comparative rates at the one and five-year periods were similar. Although no specific relative risk was assigned to Bendectin use, the authors concluded that Bendectin, when taken at a recommended dosage level, was not teratogenic. Lucille Milkovich & Bea Van den Berg, *An Evaluation of the Teratogenicity of Certain Antinauseant Drugs*, 125 Am.J.Obstetrics & Gynecology 244, 245-48 (1976).

2. ***The Boston and Harvard Study***: Six doctors from Boston University and the Harvard School of Public Health evaluated a

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OTA-BA-266, *Reproductive Health Hazards in the Workplace* 166 (1985). The higher the study's power, the stronger are its conclusions and findings regarding its outcome. If a sample population is small, however, the power of the study will likely be less. The information behind the study is less, and the confidence interval will likely span a wider range for a smaller sample group than for a larger one. The power is less for the smaller group than for the larger group, even though the confidence interval may still be set at 95 percent, because the smaller study's predictive value is lessened by a wide confidence interval range. A statistician could accordingly describe the probability of choosing an expected outcome in the large study as being greater than in the smaller study. Cohen, *Confidence in Probability*, at 398-99.

As can be seen, in may aspects, the concepts of confidence intervals, sampling sizes, population and power are mutually interdependent. For an overview of how epidemiology is used in risk assessment, see Proposed Guidelines for Assessing Female Reproductive Risk, 53 Fed.Reg. 24,834, 24,840-41 (1988).

group study of 50,282 mothers and children for Bendectin's possible effect on birth defects. Of these mothers, 1,169 took Bendectin during their first four months of pregnancy, with 79 births resulting in various birth defects. Limb defects were not specifically reported. The 49,113 mothers who were not exposed to Bendectin gave birth to 3,169 infants who had various birth defects. Overall, 4.7 percent of those mothers exposed to Bendectin gave birth to deformed infants, while 4.5 percent of non-exposed mothers did. Thus, the relative risk of birth defects for Bendectin use was 1.07 at a 95 percent confidence level. The confidence interval was not listed. Taking this into account, the authors concluded that no "statistically significant" association existed, providing no evidence that Bendectin's components -- including doxyalamine succinate -- were harmful to the fetus. Samuel Shapiro *et al.*, *Antenatal Exposure to Doxyalamine Succinate and Dicyclomine Hydrochloride (Bendectin) in Relation to Congenital Malformations, Perinatal Mortality Rate, Birth Weight, and Intelligence Quotient Score*, 128 Am.J.Obstetrics & Gynecology. 480, 481-84 (1977).

3. ***The Atlanta Study***: Over 280,000 births were monitored in the Atlanta area over a ten-year period for maternal exposure to various drugs including Bendectin. This population base was twenty times larger than that in the San Francisco study. Of 1,231 birth defects cases, 117, or 9.5 percent, of the mothers took Bendectin. Of 129 children born with limb defects, 14 (10.9 percent) had mothers who took Bendectin. The study calculated a relative risk of 1.18 at a 95 percent confidence interval between 0.65 and 2.13. However, for one subgroup of limb defects known as the "amniotic band complex," a higher relative risk -- 3.88 -- was reported. Therefore, the risk of a Bendectin-exposed mother giving birth to a child with this specific condition was almost four times greater than that which would occur in a population of non-exposed mothers. Two other forms of birth defects (herniated-brain and esophageal defects) had relative risks of 1.84 and 2.47, with 95 percent confidence levels between 0.63 and 5.37 and between 0.84 and 4.89, respectively.

For most birth defects, including limb defects, the authors determined that no "statistically significant" associations could be traced. As for the three above-mentioned possible associations, the authors noted possible confounding factors that might weaken the power of such associations, so that "the data [did] not suggest that Bendectin is causally associated" with birth defects. Jose Cordero *et al.*, *Is Bendectin a Teratogen?*, 245 JAMA 2307 (1981).

4. ***Pyloric Value Defects*****:** The highest associations found between Bendectin use and birth defects were focused not on limb defects but on pyloric stenosis (abnormal constriction of the stomach's pyloric valve). In one Yale School of Medicine study, a relative risk of 1.40 was detected between mothers using Bendectin (1,427 cases) and non-users (3,001) for birth deformities. When the survey exclusively focused on infants with pyloric valve defects, six mothers taking Bendectin gave birth to children with this defect, as opposed to 29 mothers who did not use the drug. At a 95 percent confidence interval between 1.75 and 10.75, the relative risk of this stomach valve defect was 4.33. "Thus, more than one in 10 cases of pyloric stenosis may be due to maternal use of Bendectin," although no direct causal relationship could be ascertained. Brenda Eskenazi & Michael Bracken, *Bendectin (Debendox) As a Risk Factor for Pyloric Stenosis*, 144 Am.J.Obstetrics & Gynecology 919, 921-24 (1982). The same study noted that one child with a limb reduction defect was born to a mother taking Bendectin, while five defects occurred in children of women not taking the drug. Although a relative risk of 4.19 resulted for limb defects, this was regarded as "nonsignificant" by Eskenazi and Bracken, *id.* at 923, possibly due to the smallness of the group studied and the wide range of the confidence interval.

A later study conducted by Boston University Medical Center of 13,346 births around Puget Sound tended to support Eskenazi's and Bracken's findings. In 3,385 cases involving Bendectin use, 13 babies were born with pyloric valve defects, while 13 women out of 9,511 not exposed to the drug gave birth to affected children. These findings yielded a 2.5 relative risk ratio at a 95 percent confidence interval between 1.2 and 5.2. Despite

this positive association, however, the Boston University researchers noted "the absence of any apparent biologic basis" to support the connection between Bendectin use and development of purely internal deformities like pyloric stenosis. The researchers also acknowledged that severity of the mothers' nausea could have confounded the results. Pamela Aselton *et al.*, *Pyloric Stenosis and Maternal Bendectin Exposure*, 120 Am.J.Epidemiology 251, 252-56 (1984). An earlier study by two members of the same group focused on limb disorders in the same geographic region. Of 5,255 women studied, two infants out of 1,364 born to women who used the drug had limb defects, while four infants in the 3,841 Bendectin-free mothers had defects. The study yielded a relative risk of 1.4 and a 95 percent confidence interval between 0.26 and 7.71. A related study disclosed that of 2,255 infants born to Bendectin users, two children were born with malformed limbs, compared with six similar limb defects in babies born to 4,582 non-users. From this, a relative risk of 0.9 at a 95 percent confidence level between 0.29 and 2.98 was derived. The researchers concluded this was "evidence against a strong association." Pamela Aselton & Herschel Jick, *Additional Follow-Up of Congenital Limb Disorders in Relation to Bendectin Use*, 250 JAMA 33 (1983).

5. ***The Sydney Study***: University of Sydney researchers compared pregnancy histories for mothers of 155 children born with limb reduction defects with those for the mothers of 274 control group children; 26 percent of the 429 mothers in both groups used Bendectin during the first trimester of pregnancy. The relative risk resulting was 1.1, with a 95 percent confidence interval between 0.8 and 1.5. The Australian researchers concluded that "[o]n these figures, there is no evidence that women who take [Bendectin] . . . are more likely to bear a limb-deficient child than women who do not take this drug." Janet McCredie *et al.*, *The Innocent Bystander*, 140 Med.J.Austl. 525, 526-27 (1984).

6. ***The National Institute of Health Study***: In the most recent Bendectin study, two National Institute of Health researchers evaluated 31,564 births in Northern California. Of those women 2,771 (nine percent) had used Bendectin. For 58 categories of

defects studied -- limb defects, however, were not specifically monitored -- 135 defects occurred in cases of Bendectin exposure, while 1,439 defects occurred in non-exposed cases. Relative risks were greatest in three categories: lung defects (4.6), microcephaly, *i.e.*, small head size (3.1), and cataracts (3.7). The 95 percent confidence intervals varied widely for these three categories, ranging between 1.9 to 10.9 for lung defects, 1.8 to 15.6 for microcephaly, and 1.2 to 24.3 for cataracts.

Despite these findings, the authors surmised that the three statistically significant defect groups were possibly spurious, as they were "exactly the number . . . that would have been expected by chance." How this determination was made, however, is not specified by the authors. The authors concluded that no increase in overall rates of defects existed after Bendectin use and that the three associations "are unlikely to be causal." Patricia Shiono & Mark Klebanoff, ***Bendectin and Human Congenital Malformations***, 40 Teratology 151, 152-55 (1989).

In addition to the 35 epidemiological studies, the defendant also offers as evidence the fact that no one has detected a decrease in the incidence of birth defects after Bendectin was removed from the market in 1983. Dr. Lamm so testified for the defendant based on a number of studies.

B. *Plaintiffs' Challenge to the Epidemiological Proof*

The plaintiffs claim that the defendant's 35 studies are based on samples which are too small to prove the absence of causation in light of the infrequency of instances of birth defects in general; that they do not adequately isolate limb reduction defects from other birth defects; that they do not control for many confounding factors such as smoking and the use of other drugs; that they impose a much higher level of scientific certainty of association (95 percent) than required by the preponderance of

the evidence standard of proof (*i.e.*, 51 percent);[2] and that some of the studies can be read to show some statistically significant association if a much lower level of certainty is used. In essence the plaintiffs argue that the 35 statistical studies do not prove or disprove anything concerning the relationship between Bendectin and limb reduction defects.

At least two expert witnesses for the plaintiffs attack the persuasive force of the defendant's statistical comparisons of the incidence of Bendectin-related birth defects. Dr. Glasser criticized the defendant's use of studies by Aselton, Jick, Cordero and Eskenazi as not correctly considering other birth defects, such as heart and pyloric valve defects or cleft palates, in assessing Bendectin's capacity for limb birth defects. In his affidavit, Dr. Glasser also criticized the Cordero, Eskenazi and McCredie studies for incorrectly inferring that no association existed between Bendectin use and infant limb reduction. Dr. Swan, similarly, rejected these studies' sole reliance on a relative risk of 1.0 within a 95 percent confidence interval as a basis for concluding that Bendectin does not cause birth defects in humans. Dr. Swan further claimed that several of the studies were conducted using insufficient populations or control groups, so that scientists wrongly calculated exposures to the drug. Dr. Swan viewed these and other factors as confounding the validity and power of such reports; however, both Drs. Glasser and Swan relied on these studies as the basis for their own recalculations, using a lower confidence interval that is claimed to derive a higher relative risk. Both experts concluded from their own reassessments that to a reasonable degree of epidemiological certainty, there is some association between Bendectin and limb reduction defects.

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[2] While scientists' use of confidence intervals is as a common-sense device to give professional weight to their results, such confidence intervals are not the same as the preponderance of the evidence standard of proof. This requires proving one's case by the greater weight of the evidence. Where the weight is equally divided between the plaintiff and the defendant, the party bearing the burden of proof must lose. Reduced to a percentage, this requires proof of one's case to at least 51 percent of the evidence.

Although we agree with the defendant that its epidemiological studies and Dr. Lamm's testimony constitute evidence on which a jury might ground a defendant's verdict, we agree with the plaintiffs' experts that this evidence is by no means conclusive. The defendant's claim overstates the persuasive power of these statistical studies. An analysis of this evidence demonstrates that it is possible that Bendectin causes birth defects even though these studies do not detect a significant association.

Limb reduction defects occur in such a small percentage of both Bendectin and non-Bendectin live births -- as noted, these occur in less than one in every 1,000 -- that it would take a carefully controlled comparison of a very large number of births to instill confidence in the predictive power of the outcome. Also, many of the defendant's studies apparently do not control for many factors that may be crucial for scientists to accord great weight to the studies, such as the stage of pregnancy during which the mother took Bendectin, the other drugs the mother may have taken, or other harmful conditions, natural or otherwise, that may have been part of the mother's environment.

The Bendectin epidemiological studies are examples of a large number of studies of birth defects that demonstrate significant scientific uncertainty concerning their causes. A recent epidemiological study observes that "the etiology of congenital anomalies is poorly understood, with an estimated 60 [percent] of all human birth defects having no known cause." Patricia Olshan *et al.*, *Paternal Occupation and Congential Anomalies in Offspring*, 20 Am.J.of Indus.Med. 447 (1991) (exploratory study finding a correlation between birth defects and the occupation of the father, but reasons for result yet unknown). The science of epidemiology is currently unable to identify the causes of many birth defects or to exclude from consideration many possible causes, including Bendectin and a host of other outside agents and environmental factors.

C. *Plaintiff's Proof -- Animal Studies*

The cartilage cells that later become the bones of fingers and toes begin to form in the human embryo during the fourth through eighth weeks of pregnancy. The plaintiffs' theory is that

chemical compounds in Bendectin interfere with the formation of these cartilage cells, or chondrogenesis, and that this causal relationship is shown by animal experiments. The plaintiffs' proof includes experiments with animal cells and embryos, known as *in vitro* studies, performed by developmental biologists to observe possible toxic effects on animal tissue when tested in petri dishes. Other animal experiments, *in vivo* studies, consisted of tests performed on animals such as rabbits, chickens, monkeys, rats and dogs to determine if Bendectin's ingredients created birth defects at various dosage levels. In these experiments, doxyalamine succinate, an ingredient of Bendectin, was injected into animal cells that produce or grow into cartilage that becomes the bones in which limb defects may occur. The plaintiffs' scientific hypothesis based on these studies is this: Because doxyalamine succinate interferes with cartilage cell formation in animal cells and test animals, Bendectin is "capable" of causing similar limb defects in humans. The following examples illustrate the nature and findings of these animal cell studies:

1. ***In vitro studies***: As a developmental biologist, Dr. Newman stated that he performs experiments on embryonic cells in petri dishes to determine how those cells develop and create tissue. Due to their similarities to the human embryo, chicken and mice or rat embryos are most frequently used in these studies. Limb-forming cells are removed from the embryo -- for chickens, wing and leg formation cells are used -- and are isolated in a dish, where selected cells are treated with a suspected teratogen. Changes in cell differentiation between the control group of untreated cells and the exposed group are observed and recorded.

Dr. Newman pointed to experiments on rat cells with substances similar to doxyalamine succinate. In these *in vitro* tests, various defects including limb reduction were observed. Other *in vitro* tests performed by National Institute of Health experts and relied upon by Dr. Newman found that doxyalamine succinate interfered with cartilage development in mice and chicken limb cells. In one experiment, the addition of 10 micrograms of Bendectin to an animal cell culture reduced one

of the components of cartilage cells, proteoglycan, by 30 percent. Similarly, 50 micrograms of Bendectin per milliliter of a culture reduced proteoglycan production by 50 percent, thus suggesting a strong teratogenic effect in the animal cells tested.

Like the other scientists who testify concerning animal experiments, Dr. Newman can only testify that these chemical compounds connected with Bendectin are "capable of causing" limb defects in humans, not that they do cause such defects.[3]

2. *In vivo studies*: Dr. Gross, a pathologist and veterinary medical expert with the Environmental Protection Agency, described the nature of the *in vivo* studies proffered by the plaintiffs. In these experiments, suspected teratogens are administered to pregnant female animals. Shortly before their birth, the infants are removed from the mother and studied for defects. Dr. Gross examined a variety of these studies, including Bendectin experiments performed by the defendant on rats and rabbits. In one such study, doxyalamine succinate was given daily to female rabbits at three varying dosage levels. No defects were observed at the two lower levels; however, 40 percent of the litters born to females at the highest dosage had some congenital defects observed. As dosages were increased even higher, "outright death" of animal infants occurred. Dr. Gross rejected several of Merrell Dow's other studies as being confounded by the presence of defects in the non-exposed control group while other studies indicated defects that were assessed by Dr. Gross as being compatible with teratogenicity, although not

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[3] As stated in his affidavit: "It is my opinion . . . specifically with respect to my experience with limb development and knowledge of the impact of the antihistamine Bendectin on cell function, that Bendectin is capable of interfering with the development of the limb in the human being and causing birth defects in the developing limb . . . and that Bendectin is a human teratogen." Dr. Newman states further that, although he is not a medical doctor, his review of the medical files of Brandy Turpin and her mother indicates the infant plaintiff's defects are "consistent with the effects of teratogen," with Bendectin being "capable" of being such a teratogen. Aff., Dr. Newman, *Turpin v. Merrell Dow*, No. 84-105 (E.D. Ky. Mar. 27, 1990), at 8, 10.

all of the observed defects were limb-related. Dr. Gross stated that testing animals at levels higher than human dosages and then extrapolating the results to humans was a generally accepted practice. Based on his review of the studies, Dr. Gross gave his opinion that doxyalamine succinate in Bendectin has the "capacity" to interfere with human cell development at normal dosages but could not testify that it does cause such defects.

A recognized text on teratology states the customary scientific view that "it has become axiomatic in experimental teratology that agents capable of causing any adverse biological effects can usually also be shown to be embryotoxic under the right conditions of dosage, developmental stage, and species susceptibility," and that "virtually all drugs and a great range of chemicals can indeed be shown to be embryotoxic under appropriate laboratory conditions." James Wilson, *Current Status of Teratology*, in *Handbook of Teratology* 60 (J. Wilson & C. Fraser, eds. 1977). The author concludes that to "eliminate drugs and chemicals because they can be shown to be embryotoxic at high dosage would be unacceptable" because to do so "would eliminate most drugs and many useful chemicals upon which modern society depends heavily." *Id.*

The weakness of the plaintiffs' case results from the care with which reputable scientists use animal experiments to predict causation in humans. This weakness arises from the fact that different species of animals react differently to the same stimuli for reasons not entirely understood.[4] Immune systems, nervous

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[4] Several animal studies of cortisone, for example, found that it causes severe cleft palate birth defects in several animal species, but it does not cause this effect in humans. Alfred Bongiovanni & Arthur McPadden, *Steroids During Pregnancy and Possible Fetal Consequences*, 11 Fertility & Sterility 181, 184-45 (1960) ("With doses more closely resembling those employed in medical practice," doses of cortisone led to frequent cleft palate defects in several species, especially mice, while surveys of human pregnancies demonstrated that almost none of this defect could be attributed to cortisone treatments. "It would appear, therefore, that in spite of the awesome results reported in other species, the human fetus is rarely injured by maternal treatment with corticoids."). *See also* Beverley Murphy &

systems, and metabolisms (*i.e.*, physical processing of chemical compounds) may differ greatly between species. No doubt there may be other animal experiments which, to cite one example, because of the extreme toxicity of the substance tested, would permit a reasonable jury to find that it is more probable than not that the substance causes a similar harm to humans. But Bendectin is not such a case.

The decisive weakness in the plaintiffs' animal studies is that the factual and theoretical bases articulated for the scientific opinions stated will not support a finding that Bendectin more probably than not caused the birth defect here. On summary judgment, under the doctrine of *Celotex Corp. v. Catrett*, 477 U.S. 317 (1986), and *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242 (1986), the expert evidence must show the elements required for a finding of causation. Here, except for Dr. Palmer's testimony discussed below, the plaintiffs' experts stop short of testifying that Bendectin more probably than not caused the birth defects in babies. They stop short because they have no factual or theoretical basis for a stronger hypothesis. They testify that the animal studies show that Bendectin is "capable of causing," "could cause" or its effects are "consistent with causing" birth defects, not that it probably causes birth defects in general or that it did in this case. In short, they testify to a possibility rather than a probability.

Dr. Palmer, a medical doctor, is the only witness who testified in his affidavit that Bendectin caused Brandy Turpin's defects. He stated:

> It is my opinion . . . that [animal *in vivo* and *in vitro* studies, and epidemiological and other human data] shows that Bendectin and specifically its component,

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Charlotte Branchard, *Fetal Metabolism of Cortisol*, 5 Current Topics in Experimental Endocrinology 197, 221 (1983) (injections of cortisone will precipitate labor in pregnant sheep, cows, goats, rabbits, and rats; this does not occur in humans), and Elwyn Grimes, Jamil Fayez & Gerald Miller, *Cushing's Syndrome and Pregnancy*, 42 Obstetrics & Gynecology 550, 558 (1973) (accepting findings of the Bongiovanni and McPadden report).

> doxyalamine succinate, has teratogenic properties . . . . I have also examined the medical records pertaining to Brandy Turpin and it is my opinion . . . . that Bendectin did cause the limb defects from which she suffers.

We cannot find, however, that this testimony is anything more than a personal belief or opinion. The grounds for his opinion are subject to the same criticism as the animal studies and epidemiological reanalyses submitted by the plaintiffs' other experts: the evidence cited in support of his conclusion is insufficient to meet the plaintiffs' burden of proof. Dr. Palmer does not testify on the basis of the collective view of his scientific discipline, nor does he take issue with his peers and explain the grounds for his differences. Indeed, no understandable scientific basis is stated. Personal opinion, not science, is testifying here. Dr. Palmer's own expressed skepticism as to the value of extrapolating human conclusions from animal studies further confounds the issue. Upon analysis, we conclude that Dr. Palmer's conclusions go far beyond the known facts that form the premise for the conclusion stated. This conclusion so overstates its predicate that we hold that it cannot legitimately form the basis for a jury verdict. Beyond that Dr. Palmer's opinion testimony, to the extent that it is personal opinion as described above, is inadmissible. Fed.R.Evid. 703; *see also Viterbo v. Dow Chem. Co.*, 826 F.2d 420, 423-24 (5th Cir. 1987) (physician's unsupported personal opinion of causation held inadmissible), and *Calhoun v. Honda Motor Co.*, 738 F.2d 126, 131-32 (6th Cir. 1984) (expert testimony must be based on the evidence, so as to be removed from the realm of guesswork and speculation).

We do not mean to intimate that animal studies lack scientific merit or power when it comes to predicting outcomes in humans. Animal studies often comprise the backbone of evidence indicating biological hazards, and their legal value has been recognized by federal courts and agencies. *See, e.g., International Union, UAW v. Johnson Controls, Inc.*, 111 S. Ct. 1196, 1215 (White J., concurring) (*citing Industrial Union Dep't v. American Petroleum Institute*, 448 U.S. 607, 657 n.64 (1980)); *Environmental Defense Fund, Inc. v. EPA*, 548 F.2d 998, 1006-07 (D.C. Cir.

1976); Proposed Guidelines for Assessing Female Reproductive Risk, 53 Fed.Reg. 24,834, 24,836-39 (1988) (discussing the use of animal studies to identify and assess reproductive hazards for human females); Proposed Guidelines for Assessing Male Reproductive Risk, 53 Fed.Reg. 24,850, 24,853-60 (1988) (discussing the use of animal studies to identify and assess reproductive hazards for human males).

Here, the record's explanation of the animal studies is simply inadequate. Although the animal studies themselves may have been scientifically performed, the exact nature of these tests is explained only in general terms. The record fails to make clear why the varying doses of Bendectin or doxyalamine succinate given to the rats, rabbits and *in vitro* animal cells would permit a jury to conclude that Bendectin more probably than not causes limb defects in children born to mothers who ingested the drug at prescribed doses during pregnancy. The analytical gap between the evidence presented and the inferences to be drawn on the ultimate issue of human birth defects is too wide. Under such circumstances, a jury should not be asked to speculate on the issue of causation.

Accordingly, the judgment of the District Court is **AFFIRMED**.

APPENDIX B

GARY TURPIN, BETTY TURPIN, Individually and as Parent and Natural Guardian of Brandy Turpin, a Minor, *Plaintiffs*, v. MERRELL DOW PHARMACEUTICALS, INC., *Defendant*.

Civil Action No. 84-105

UNITED STATES DISTRICT COURT
For The Eastern District Of Kentucky

April 25, 1990, Decided

MEMORANDUM

SILER, Chief Judge.

This action is before the Court on the motion of the defendant Merrell Dow Pharmaceuticals Inc. (Merrell Dow) for summary judgment pursuant to Fed.R.Civ.P. 56. After reviewing the voluminous materials submitted by the parties, including affidavits of experts, trial and deposition transcripts, excerpts of transcripts, summaries of published scientific studies, and numerous decisions of other courts regarding the same or similar issues, the Court is convinced that no genuine issues of material fact exist and the case can therefore be decided as a matter of law. Thus, for the reasons stated below, Merrell Dow's motion for summary judgment will be granted.

It appears from the record that the parties do not dispute the facts out of which this action arose. Brandy Turpin, minor-plaintiff, was born on February 27, 1982, to plaintiff-parents, Gary and Betty Turpin. Brandy was born with various deformities to both hands and feet which have required several surgical procedures to partially correct. Betty Turpin ingested the drug Bendectin during her pregnancy with Brandy. Bendectin was a prescription pharmaceutical product manufactured by Merrell Dow, and prescribed for the treatment of nausea and vomiting during pregnancy. Bendectin was the only anti-nauseant approved by the Food and Drug Administration (FDA) to combat

"morning sickness" experienced by mothers during pregnancy. Merrell Dow removed the product from the marketplace in 1983 due the increased costs of litigation surrounding the drug. The plaintiffs assert that Betty Turpin's Bendectin ingestion caused her daughter's birth defects. Merrell Dow argues that the plaintiffs can submit no evidence that supports the contention that a causal association between Bendectin and birth defects exists. Thus, the primary issue to be decided by the Court is whether the plaintiffs have submitted sufficient evidence that Bendectin is teratogenic (capable of causing birth defects) to survive a grant of summary judgment.

I.

Rule 56(c) of the Federal Rules of Civil Procedure provides that after an adequate opportunity for discovery, *see Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986); *Anderson v. Liberty Lobby*, 477 U.S. 242, 250 n. 5 (1986), the moving party shall be granted summary judgment when it appears that "there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." "[A] party seeking summary judgment always bears the initial responsibility of informing the district court of the basis for its motion, and identifying those portions of 'the [record]' which it believes demonstrates the absence of a genuine issue of material fact." *Celotex, supra*, 477 U.S. 317 at 323. However, there is "no express or implied requirement in Rule 56 that the moving party support its motion with affidavits or other similar materials, *negating* the opponent's claim." *Id.* (Emphasis in original.)

Once a properly supported motion for summary judgment is made, "the nonmovant must go beyond the pleadings and by affidavits or by 'depositions, answers to interrogatories, and admissions on file' designate 'specific facts showing that there is a genuine issue for trial.'" *Potters Medical Center v. City Hospital Association*, 800 F.2d 568, 572 (6th Cir. 1986), *quoting* Fed.R.Civ.P. Rule 56(c),(e). *See also Anderson, supra*, 477 U.S. 242 at 248-49.

The standard for granting summary judgment is identical to the standard for a directed verdict under Fed.R.Civ.P. 50(a), "which is that the trial judge must direct a verdict if, under the governing law, there can be but one reasonable conclusion as to the verdict. . . . If reasonable minds could differ as to the import of the evidence, however, a verdict should not be directed." *Anderson, supra*, at 250-51. "The evidence must be viewed in a light most favorable to the party opposing summary judgment and that party must be given the benefit of all reasonable inferences." *Potters, supra*, at 572. *See also Matsushita Electric Industrial Co. v. Zenith Radio Corp.*, 475 U.S. 574 (1986); *Bouldis v. United States Suzuki Motor Corp.*, 711 F.2d 1319, 1324 (6th Cir. 1983).

II.

Merrell Dow contends that human epidemiology studies demonstrate that there is an absence of any evidence connecting Bendectin with birth defects. To support its position, Merrell Dow submitted the summary of over thirty (30) separate human epidemiology studies, none of which demonstrated any connection between birth defects and Bendectin ingestion. The plaintiffs have submitted contrary testimony. The defendant urges the Court to conclude that this expert testimony, tendered by the plaintiffs, is inadmissible under Fed.R.Evid. 703, as their opinions are not based on facts or data "of a type reasonably relied upon by experts in the particular field." Fed.R.Evid. 703. Merrell Dow argues that as the plaintiffs have offered no confirmed, statistically significant, epidemiological data establishing a causal relationship between Bendectin use and birth defects, summary judgment is appropriate.

The plaintiffs attempt to prove Bendectin's teratogenicity through the presentation of expert opinion testimony of seven scientists representing a variety of fields relating to birth defects including pathology, epidemiology, chemistry, developmental biology, pharmacology, toxicology, embryology, teratology, and dysmorphology. These experts include Drs. Johannes Thiersch, Shanna Swan, Stewart L. Newman, Frederick Crescitelli,

Andrian Gross, Jay Glasser, and John Palmer. While testifying to Bendectin's teratogenicity, these experts draw their opinions from four areas of evidence, studies of analogous chemical structures, *in vivo* and *in vitro* animal studies, and from the criticism and reanalysis of various of the epidemiological studies submitted by the defendants.

A review of the record reveals the content of each expert's trial testimony. Dr. Johannes Thiersch, a specialist in pathology and pharmacology, would testify that a chemical's composition and its physiological activity is a decisive factor in teratogenic investigations. Dr. Shanna Swan, an epidemiologist and biostatistician, would testify considering all available data, and using the methodology reasonably relied upon by epidemiologists, that with a reasonable degree of medical certainty Bendectin is associated with limb reduction defects. Dr. Stewart Newman, a specialist in developmental, cell, and molecular biology, would testify based on *in vitro* studies and the pharmacological aspects of Bendectin, that Bendectin is a human teratogen capable of causing birth defects in the developing limbs of human beings. Dr. Adrian Gross, a veterinarian with experience in pathology and toxicology, would testify based on animal studies that Bendectin is teratogenic. Dr. Jay Glasser, a professor of biometry and computer science, with other teaching experience in epidemiology, statistics and biostatistics, would testify based on data reasonably relied upon by biometrists, epidemiologists, and biostatisticians, that Bendectin was epidemiologically statistically associated with limb defects. Dr. Frederick Crescitelli, a biologist with accessory training in physics and chemistry, would testify based on analysis of Bendectin's antihistaminic component, that Bendectin is a teratogen. Dr. John Palmer, a physician and pharmacology professor, would testify based on pharmacological data, animal studies, *in vitro* studies, epidemiological data and other human data, that Bendectin, specifically its antihistaminic component, has teratogenic properties. Dr. Palmer also examined the medical records pertaining to Brandy Turpin and would testify that within a reasonable degree of medical certainty Bendectin was taken during a period of time

that would affect the cells that produce normal limbs in Brandy Turpin and that Bendectin did in fact cause the limb defects from which she suffers. The plaintiffs also submitted materials regarding the credentials and testimony of Dr. Alan Done, Dr. Wayne Snodgrass, and Dr. W.G. McBride, but did not indicate that their testimony would be offered at trial. *See Daubert v. Merrell Dow*, 727 F. Supp. 570, 574-75 (S.D.Cal. 1989) (outlining more fully the proffered testimony of each expert above, with the exception of Dr. Crescitelli).

III.

Fed.R.Evid. 703 requires that the grounds relied upon in the formulation of an expert opinion be of "a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject." Fed.R.Evid. 703. "Whether an expert's opinion has an adequate basis, and whether without it an evidentiary burden has been met, are matters of law for the court to decide." *Richardson v. Richardson-Merrell*, 857 F.2d 823, 829 (D.C.Cir. 1988), *cert. denied*, 110 S. Ct. 218, 58 U.S.L.W. 3219 (1989); *see United States v. Kozminski*, 821 F.2d 1186, 1194 (6th Cir. 1987), *aff'd*, 487 U.S. 931 (1989). In *Kozminski*, the Sixth Circuit developed a four-part test that must be satisfied for expert testimony to be admissible. To be admissible the testimony must: (1) be by a qualified expert; (2) be on a proper subject; (3) be in conformity to a generally accepted explanatory theory; (4) and have a probative value which outweighs any prejudicial effect. *Kozminski, supra*, at 1194. *See also Novak v. United States*, 865 F.2d 718, 721 (6th Cir. 1989) (applying test in a civil action); *Sterling v. Velsicol Chemical*, 855 F.2d 1188, 1208-09 (6th Cir. 1988) (applying *Kozminski* test). The plaintiffs' experts' testimony, while satisfying three prongs of the test, fails the third prong in that their testimony is not in conformity with a generally accepted explanatory theory in light of the overwhelming epidemiological data governing the non-teratogenicity of Bendectin.

As the Sixth Circuit has made no pronouncement that epidemiological studies form the sole basis upon which experts

may reasonably rely when forming an opinion on a drug's teratogenicity, the Court must look to other circuits for guidance. *See In re Richardson Merrell, Inc. Bendectin Products Liability Litigation*, 624 F. Supp. 1212 (S.D.Ohio 1985), *aff'd*, 857 F.2d 290 (6th Cir. 1988), *cert. denied, Hoffman v. Merrell Dow*, 488 U.S. 1006, 109 S. Ct. 788 (1989) (Although Judge Rubin allowed the presentation of "testimony of eminently qualified and highly credible experts" on both sides, no ruling was made regarding the third prong of the *Kozminski* test. In fact, defense counsel admits no objection to the admissibility of the plaintiffs' experts was raised, nor was there a motion for directed verdict based upon the insufficiency of evidence in that action.).

Three circuits have rejected similar proof submitted by the plaintiffs in this action, holding that the evidence was insufficient to support a finding of Bendectin's causal connection with birth defects. In *Richardson v. Richardson-Merrell, Inc.*, 857 F.2d 823 (D.C.Cir. 1988), *cert. denied*, 110 S. Ct. 218, 58 U.S.L.W. 3219 (1989), the D.C. Circuit affirmed the trial judge's holding that the evidence presented at trial was insufficient to support the jury's determination that Bendectin caused the minor-plaintiff's limb reduction defects. In ruling that the plaintiff's relevant evidence in causation was inadmissible under Fed.R.Evid. 703, the court looked behind the expert's ultimate conclusion that Bendectin causes birth defects and analyzed the adequacy of its foundation. *Id.* at 829. The court examined the probative value of the four types of data relied upon by the plaintiff's expert, Dr. Alan Done, and concluded:

> These three types of studies then -- chemical, *in vitro*, and *in vivo* -- cannot furnish a sufficient foundation for a conclusion that Bendectin caused the birth defects at issue in this case. Studies of this kind, singly or in combination, are not capable of proving causation in human beings in the face of the overwhelming body of contradictory epidemiological evidence. Perhaps mindful of this, the last type of evidence considered by Dr. Done consisted of epidemiological studies. When such studies are available and relevant, and particularly when they are numerous and span a significant period of

> time, they assume a very important role in determinations of questions of causation.

Id. at 830. Rejecting Dr. Done's epidemiological data, the court wrote:

> Dr. Done further admitted that no one who has published work on Bendectin has concluded that there is a statistically significant association between Bendectin and limb reduction defects of the type at issue in this case. Only by recalculating the data was Dr. Done able to obtain what he deems a statistically significant result. Moreover, the studies rejected by Dr. Done had been published in peer-reviewed scientific journals, while Dr. Done has neither published his recalculations nor offered them for peer review. (Footnotes omitted.)

Id. at 831. The court further distinguished its case from *Ferebee v. Chevron Chemical*, 736 F.2d 1529 (D.C.Cir.), *cert. denied*, 469 U.S. 1062 (1984), where the defendant's argument that the testimony of plaintiff's experts was inadmissible was rejected. The court stated that in *Ferebee* the causation issue was novel and "stand[s] at the frontier of current medical and epidemiological inquiry," whereas the wealth of published epidemiological data involving Bendectin was a great distance from the "frontier". *Id.* at 832. *See also Ealy v. Richardson-Merrell*, 897 F.2d 1159 (D.C.Cir. 1990) (The court followed Richardson and reversed a finding for the plaintiffs on the issue of liability holding that none of the evidence relied upon by the Ealys' experts, either singly or in combination, provided an adequate scientific foundation to render their opinions on human causation admissible. Several of the plaintiffs' experts in this action were the same as in the Ealy trial, including Drs. Gross, Newman, Swan, and Thiersch. In fact, the plaintiffs' support their position in this action with several transcript excerpts and affidavits from the Ealy case.). *See also* Elliott, *Toward Incentive-Based Procedure: Three Approaches for Regulating Scientific Evidence*, 69 Boston Univ.L.R. 487, 498-99 (1989) (approving the Richardson rule).

The Fifth Circuit reversed a lower court's entry of a judgment on a jury verdict in favor of the plaintiffs, holding that the lack of conclusive epidemiological proof was fatal to the plaintiffs' case. *Brock v. Merrell Dow*, 874 F.2d 307, *mod.* 884 F.2d 166 (5th Cir. 1987). The court rejected the plaintiffs' *in vivo* and *in vitro* studies, chemical analysis evidence, and reanalysis of existing epidemiological data, offered by Drs. Glasser, Newman, Thiersch (all present in this action), Snodgrass, Glauser and McBride. The court held:

> We find, in this case, the Brocks' failure to present statistically significant epidemiological proof that Bendectin causes limb reduction defects to be fatal to their case. While we do not hold that epidemiologic proof is a necessary element in all toxic tort cases, it is certainly a very important element. This is especially true when the other evidence is in the form of animal studies of questionable applicability to humans.

Id. at 313, *mod.* 884 F.2d 167. The court encouraged district judges "faced with medical and epidemiologic proof in subsequent toxic tort cases to be especially vigilant in scrutinizing the basis, reasoning, and statistical significance of studies presented by both sides." *Id.* at 167.

In *Lynch v. Merrell-National Laboratories*, 646 F. Supp. 856, 867-68 (D.Mass. 1986), *aff'd*, 830 F.2d 1190 (1st Cir. 1987), the district court granted summary judgment for the defendants. The plaintiffs' evidence, including reanalysis criticizing the methodology of other epidemiological studies, extrapolations from *in vivo* and *in vitro* animal studies, and studies of analogous chemical structures, was ruled inadmissible by the court, under Fed.R.Evid. 703:

> [A] careful review of the material before this Court indicates that the only relevant, probative, and non-misleading evidence on the issue of Bendectin's role in the causation of birth defects are the controlled observations of human beings, documented in more than 25 published epidemiological studies. The data from these studies do not indicate any statistically significant association between Bendectin and

> . . . birth defect[s] . . . . This Court finds that the evidence submitted by the plaintiffs in support of their expert testimony does not comport with the requirements of the Federal Rules of Evidence. Absent admissible and competent expert testimony grounded on evidence comporting with the requirements of the Federal Rules of Evidence, the plaintiffs cannot raise a genuine issue of material fact concerning Bendectin . . . [and] the causation of . . . birth defect[s].

Lynch, supra, at 867. The First Circuit affirmed the lower court's decision after carefully analyzing the proffered testimony of Drs. Swan and Done. *Lynch, supra*, at 1194-96.

In addition to *Richardson, Brock* and *Lynch*, other courts have ruled as a matter of law the evidence supporting Bendectin's teratogenicity was insufficient. *See Daubert v. Merrell Dow*, 727 F. Supp. 570 (S.D.Cal. 1989) (The court granted defendant's motion for summary judgment where evidence from Drs. Gross, Newman, Swan, Glasser, Thiersch and Palmer, was identical to their proffered testimony in this action. Following Brock, Richardson and Lynch, the court held epidemiological studies to be the most reliable evidence of causation and rejected the proffered chemical, *in vitro* and *in vivo* studies, and reanalysis of epidemiological studies.); *Hull v. Merrell Dow*, 700 F. Supp. 28 (S.D.Fla. 1988) (Summary judgment was granted as no genuine issue of fact as to causation existed. The motion was unopposed as the plaintiffs were unrepresented by counsel at the motion's filing.); *DeLucca v. Merrell Dow*, Civ. No. 87-226 (D.N.J. June 12, 1989) (Court granted summary judgment after similar evidence was excluded under Fed.R.Evid. 703.); *Monahan v. Merrell Dow*, No. 83-3108-WD (D.Mass. December 18, 1987) (Relying on *Lynch*, the court granted defendant's motion for summary judgment.); *DePyper v. Navaro*, No. 83-303-467NM (Civ.Ct. Wayne Co., Mich. March 10, 1990) (State court excluded similar evidence, including testimony of Drs. Swan and Glasser in granting defendant's motion for summary judgment.). *See also Wilson v. Merrell Dow*, 893 F.2d 1149, 1155 (10th Cir. 1990) (The lower court's judgment on a jury verdict affirmed for defendant, concluding that the defendant's evidence was "perhaps

enough to sustain a directed verdict under *Brock, Richardson* and *Lynch.*"); *In re Paoli R.R. Yard PCB Litigation*, 706 F. Supp. 358, 369 (E.D.Pa. 1988) (Although this involved PCB exposure and not Bendectin, the court relied heavily on epidemiological data showing no connection between PCB exposure and the plaintiffs' injuries. The court excluded animal study evidence under Fed.R.Evid. 703 and granted summary judgment for defendants. *Ramirez v. Richardson Merrell*, 85-1504 (E.D.Pa. September 4, 1986); and *Lanzilotti v. Merrell Dow*, 82-0183 (E.D.Pa. July 10, 1986), Bendectin cases in which summary judgment was denied, were cited by the court, although it relied on *Richardson* and *In re "Agent Orange"*, 611 F. Supp. 1221 (E.D.N.Y. 1985); *aff'd on other grounds*, 818 F.2d 187 (2d Cir. 1987), *cert. denied*, 108 S. Ct. 2598 (1988), in evaluating the proffered evidence.).

IV.

The plaintiffs argue that Merrell Dow's proffered recitation of authority is not applicable to this case. However, the affidavits and testimony of the experts in this action were submitted from other cases. Identical testimony was rejected in *Lynch* (Dr. Swan), *Brock* (Drs. Newman, Glasser and Thiersch), *Ealy* (Drs. Gross, Newman, Swan, Thiersch), *DePyper* (Drs. Swan and Glasser), and *Daubert* (Drs. Thiersch, Swan, Newman, Gross, Glasser, Palmer). The *in vivo, in vitro*, chemical and epidemiological data relied on here has been ruled inadequate as a matter of law to support a finding that Bendectin is teratogenic. *See Richardson, supra, Brock, supra, Lynch, supra.*

While the court was not cited a case referring the testimony of Dr. Frederick Crescitelli, his proffered testimony based on chemical studies, *in vivo* and *in vitro* animal studies, adds nothing new and falls far short of "new and statistically significant studies . . . which would give a jury a firmer basis on which to determine the issue of causation." *Brock, supra*, at 167; *Richardson, supra; Lynch, supra.*

All the plaintiffs' experts would testify, in some form or fashion, that the data they relied on to formulate their opinion that Bendectin is teratogenic is of the type that is generally and reasonably relied upon in their particular fields. The Court will not rehash the rationale for rejecting this assertion with regard to the animal studies and chemical studies, as numerous opinions have accurately concluded that they are inadequate and insufficient to support, by a preponderance of the evidence, the conclusion that a causal relationship exists between birth defects and Bendectin. *See Brock, supra*; *Richardson, supra*; *Lynch, supra*.

However, to explain why the defendant's epidemiological data are admissible, where the epidemiological data of the plaintiffs' are not, there are distinct differences between the thirty (30) epidemiological studies, all finding no statistically significant relationship between Bendectin and birth defects, submitted by Merrell Dow and the proffered testimony of Drs. Swan and Glasser. Dr. Swan merely reanalyzes and recalculates existing epidemiological data to support a conclusion of a statistically significant increased risk between exposure to Bendectin and birth defects. Dr. Glasser is not an epidemiologist, medical doctor, or teratologist. He has published no articles on Bendectin, performed no epidemiological studies on Bendectin, and has admitted that no epidemiological study has revealed a statistically significant association between Bendectin and limb reduction defects, yet he concludes that it is more likely than not that a statistically significant association exists. The conclusions of Drs. Swan and Glasser have never been *refereed* or published in peer-reviewed scientific journals. *See Lynch, supra*, at 1195; *Brock, supra*, at 312. *See also Richardson, supra*, at 831 (similar data furnished by Dr. Done rejected). Therefore, the Court, following *Brock*'s mandate to scrutinize the basis, reasoning, and statistical significance of epidemiologic studies, finds the testimony of Drs. Swan and Glasser inadmissible under Fed.R.Evid. 703.

The plaintiffs rely on several cases which give more deference to expert testimony than *Brock, Lynch,* and *Richardson.*

However, the Court is persuaded that the prevailing school of thought governing expert testimony in Bendectin cases is best exemplified by *Brock*. *See Daubert, supra*, at 572. *Compare Oxendine v. Merrell-Dow*, 506 A.2d 1100 (D.C. 1986) (*Oxendine I*); and *Oxendine v. Merrell-Dow*, 563 A.2d 330 (D.C. 1989) (*Oxendine II*) (These cases allowed the introduction of expert opinion including Dr. Done's testimony. However, the *Richardson* opinion specifically rejected *Oxendine*'s reasoning and noted the differences between state and federal rules of evidence regarding admissibility. *Richardson, supra*, at 825 n.9.); *Ealy v. Richardson Merrell*, C.A. 83-3504 (D.D.C. 1987) (Jury returned a verdict for $20 million in compensatory damages and $75 million in compensatory damages and $75 million in punitive damages for plaintiff. However, this decision was reversed by *Ealy v. Richardson-Merrell*, Nos. 87-7214 and 87-7219 (D.C.Cir. March 9, 1990)); *In re Bendectin Litigation*, supra (The issue of admissibility of expert testimony was not squarely before the court.). Although the plaintiffs cite other authority, the Court finds them to be in the minority, and only the state case of *Oxendine* has been subjected to appellate review and survived.

The plaintiffs assert that these cases provide the basis for denying the defendant's summary judgment motion as they refute the contention that no reasonable jury could find in favor of the plaintiffs. However, the evidence considered by those juries varies sharply from the relevant admissible evidence that survives this Court's ruling that the plaintiffs' *in vivo*, *in vitro* animal studies, chemical studies, and human data are inadmissible under Fed. R.Evid. 703. While reasonable jurors can, and did, find for the plaintiffs in other opinions, *see Oxendine, supra*, no reasonable jury could find that a causal connection exists between Bendectin and birth defects in this action.

The plaintiffs cite *In re Bendectin*, Cons. Case. No. Misc. 85-0996 (E.D. Mich. January, 1990); *Wilson v. Merrell Dow*, Case No. 82-C-710-E (N.D. Okla. March 1, 1990); *Comeau v. Richardson-Merrell*, C.A. No. 84-0963N (D.Mass. March 1, 1990); and *Barton v. Richardson-Merrell*, Case No. C85-0028J

(D.Utah March 2, 1990), as support that summary judgment is inappropriate. However, these orders do not mention the evidence the courts considered in reaching their decision. The bare fact that summary judgment was denied without viewing the record, would force this Court to guess the basis for those courts' decision. Therefore, this authority is not persuasive.

CONCLUSION

> If Rule 703 is to be of any limit on the ability of expert witnesses to give their opinions, a court must be permitted to examine the bases of the proffered opinions. Otherwise any case in which an expert was willing to use two sets of magic words would always survive motions for summary judgment and directed verdict. As long as the expert was willing to say "to a reasonable degree of scientific certainty" and "the basis of my opinion is X, on which experts in my field reasonably rely," every case requiring expert testimony would get to the jury. If a court is not permitted to examine the basis of an expert's opinion in order to rule on the admissibility of that opinion, then Rule 703 should read: "An expert may cite as the basis of his opinion anything he likes."

In re Paoli R.R. Yard PCB Litigation, supra, at 368. *See also Brock, supra*, at 167.

In light of over thirty (30) epidemiological studies concluding that no statistically significant association exists between Bendectin and human birth defects, and after closely scrutinizing the bases of the proffered opinions of the plaintiffs' experts, this Court concludes that the testimony is inadmissible under Fed.R. Evid. 703. Furthermore, even if admissible, these opinions only support the conclusion that it is possible that Bendectin is teratogenic, and not more likely or probable than not that a causal relationship exists between Bendectin and human birth defects. Even viewing the record in the light most favorable to the nonmoving party, the plaintiffs have failed to meet their burden. Thus, summary judgment is appropriate.

The Court is not ruling that only epidemiological data is admissible when examining the question of a drug's teratogenicity. Experts may rely on other types of data when framing their opinions. However, something more than the animal studies, analogous chemical studies, and criticisms of the epidemiological data, presented in this action, must be submitted. Until that occurs, or until new and conclusive medical and epidemiological studies emerge which give a jury a firmer basis on which to determine the issue of causation, *see Brock, supra*, at 315, courts must rely on the current data that no statistically significant association between Bendectin and human birth defects exist.

Accordingly, Merrell Dow's motion for summary judgment will be granted.

ORDER

In accordance with Memorandum of even date, it is hereby

ORDERED that the defendant's motion for summary judgment be and is granted.

This 25 day of April, 1990.

/s/
EUGENE E. SILER, JR.
CHIEF JUDGE

APPENDIX C

MICHIGAN SUPREME COURT

LAWRENCE R. DePYPER, SR., Individually;
and JANE N. DePYPER, Individually, and as
Next Friend of LAWRENCE R. DePYPER, JR.,
Plaintiffs-Appellees,

v.

PAUL F. NAVARRO, D.O.;
PAUL F. NAVARRO, D.O., P.C.,
Defendants,

and

MERRELL DOW PHARMACEUTICALS, INC.,
Subsidiary of DOW CHEMICAL COMPANY;
MERRELL NATIONAL LABORATORIES, INC.,
Defendants-Appellants.

SC: 92174, 92409
COA: 116390
LC: 83 303467 NM

Entered: April 21, 1992

ORDER

On order of the Court, the application for leave to appeal and the delayed application for leave to appeal are considered, and they are DENIED, because we are not persuaded that the questions presented should now be reviewed by this Court.

Riley, J., would grant leave to appeal.

STATE OF MICHIGAN
COURT OF APPEALS

LAWRENCE R. DePYPER, SR., Individually;
and JANE N. DePYPER, Individually, and as
Next Friend of LAWRENCE R. DePYPER, JR.,
Plaintiffs-Appellants,

v.

PAUL F. NAVARRO, D.O.;
PAUL F. NAVARRO, D.O., P.C.,
MERRELL DOW PHARMACEUTICALS, INC.,
Subsidiary of DOW CHEMICAL COMPANY;
MERRELL NATIONAL LABORATORIES, INC.,
Defendants-Appellants.

No. 116380

May 9, 1991

Before: Holbrook, Jr., P.J., and Wahls and T.G. Kavanagh, JJ.

PER CURIAM.

Plaintiffs' suit alleging that the limb reduction birth defects suffered by plaintiff minor, Lawrence R. DePyper, Jr., were caused by the ingestion of Bendectin, a prescription drug developed and marketed by defendant, Merrell-Dow Pharmaceuticals, Inc., and its predecessors, was dismissed on defendants' motion for summary disposition.

The trial court granted the motion on two bases: 1) on its conclusion that plaintiffs could not produce at trial admissible or sufficient evidence that Bendectin is a teratogen capable of causing the type of birth defects present here and also 2) that even if such proof could be produced, the mother's pregnancy here had progressed too far for the ingestion of Bendectin to have been a proximate cause of the injuries. We reverse.

1. *Admissibility of the Proffered Expert Testimony*

The trial court based her conclusion on the admissibility of the proffered expert opinion on the authority and reasoning of the court in *Lynch v. Merrell-National Laboratories*, 830 F.2d 1190 (CA 1, 1987), and *Richardson v. Richardson-Merrell, Inc.*, 649 F.Supp 799 (DDC, 1986), *aff'd* 827 F.2d 823 (CADC, 1988), *cert den* ___ US ___; 110 S.Ct 218; 107 L.Ed.2d 171 (1989).

We are satisfied that the evidentiary rule of those cases does not comport with Michigan jurisprudence.

Michigan still follows the so-called *Davis/Frye* rule which requires that to be admissible expert testimony concerning a novel form or application of scientific evidence must be shown to have general scientific acceptance among impartial and disinterested experts in the field.

In this case the field is teratology. The *Davis/Frye* inquiry must then be: "Do impartial and disinterested experts in the field of teratology generally accept the methodology employed by plaintiffs' expert in assessing the impact of *in vivo*, *in vitro*, chemical structure and animal studies in determining teratogenicity?

If so, the expert's opinion is admissible -- otherwise it is not.

Here the trial court said,

> Unable to prove directly how Bendectin harmed plaintiff minor, plaintiffs unavoidably rely on circumstantial evidence to establish the requisite causal link. Through the testimony of experts in a variety of disciplines, including pharmacology, embryology, veterinary medicine, and pediatrics, plaintiffs primarily (i) seek to prove that Bendectin is capable of causing limb reduction defects by comparing Bendectin to other known teratogenic agents on the basis of analogous chemical structure, and (ii) introducing the results of *in vitro* and *in vivo* animal studies. Cross-examination of these experts invariably elicited testimony that (i) chemical resem-

> blance does not necessarily mean similar chemical activity, and (ii) differences in genetic make-up and metabolic rate, together with the inordinately large dosages typically administered, cast doubt on the scientific validity of animal studies when used to predict human physiological response. Because this evidence is identical to that described and rejected in *Lynch*, and *Richardson*, as capable of proving causation, singularly or collectively, *Lynch*, 830 F.2d at 1194 (citations omitted), further discussion is unwarranted.

In our view, without the *Davis/Frye* inquiry suggested above (which was not made here -- nor in *Lynch* and *Richardson*, *supra*) the court's ruling is premature.

2. *Time of Ingestion and Probable Cause*

Both the dates of conception and the ingestion of Bendectin are matters of fact about which there is conflicting evidence and which should be determined by the jury.

Accordingly the decision of the trial court is reversed and the case remanded for further proceedings consonant herewith.

/s/Donald E. Holbrook, Jr.
/s/Myron H. Wahle
/s/Thomas Giles Kavanagh

APPENDIX D

IN THE DISTRICT COURT OF
NUECES COUNTY, TEXAS
214TH JUDICIAL COURT

EARNEST HAVNER & MARILYN HAVNER
ON BEHALF OF THEIR MINOR CHILD KELLY HAVNER

VS.

MERRELL DOW PHARMACEUTICALS, INC.

CAUSE NO. 88-3915-F

FINAL JUDGMENT

ON THE 3rd day of September, 1991, came on to be heard the above-entitled and numbered cause and Ernest and Marilyn Havner as Representatives and Next Friend of Kelly Havner, the Plaintiffs, appeared in person and by attorney of record, and announced ready for trial, and Merrell-Dow Pharmaceuticals, Inc., the Defendant, appeared in person and by attorney of record and announced ready for trial, and the jury having been previously demanded, a jury consisting of twelve (12) good and lawful jurors was duly impaneled and the case proceeded to trial.

At the conclusion of the evidence, the Court submitted the case to the jury on questions and instructions. The Charge of the Court, including the questions submitted to the jury, and the verdicts of the jury, are incorporated herein for all purposes by reference. After the jury returned their verdicts, Plaintiffs moved the Court to enter a judgment reflecting the full amount of the jury verdicts, actual damages of Three Million Seven Hundred Fifty Thousand Dollars ($3,750,000.00), prejudgment interest at ten percent (10%) simple interest on said amount from the date of the filing of the Original Petition in this matter, July 15, 1988, until the day preceding entry of judgment and punitive damages in the amount of Thirty Million Dollars ($30,000,000).

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and moved the Court to rule that Section 41.007 of the Texas Rules of Civil Practice & Remedies Code is unconstitutional or alternatively, Defendant Merrell-Dow waived said limitation of that statute on the amount of punitive damages by failing to properly and specifically plead it, or, alternatively, moved for entry of judgment on the verdict to include prejudgment interest on the actual damages of Three Million Seven Hundred Fifty Thousand Dollars ($3,750,000.00) to run from the date of the filing of the Original Petition until the day preceding entry of judgment and for punitive damages in the amount of four (4) times the actual damages, said sum being Fifteen Million Dollars ($15,000,000.00). Defendant, Merrell-Dow moved the Court to render Judgment Non Obstante Veredicto reflecting a judgment that Plaintiffs take nothing as to their claims.

The Court, having considered the motions of Plaintiffs and Defendant, and it appearing to the Court that the verdicts of the jury were for the Plaintiffs and against Defendant, Merrell-Dow, that there is evidence of probative force to sustain the verdicts of the jury, and that an instructed verdict in favor of the Defendant would not have been proper regarding the questions submitted to the jury, judgment should be rendered on the verdicts in favor of the Plaintiffs and against the Defendant. IT IS THEREFORE

ORDERED, ADJUDGED and DECREED by the Court that Plaintiffs' Motion for Entry of Judgment reflecting actual damages of Three Million Seven Hundred Fifty Thousand and no/100 Dollars ($3,750,000.00), prejudgment interest on actual damages from July 15, 1988 until the day preceding the entry of this judgment and exemplary damages in the amount of four time the actual damages, said sum being Fifteen Million Dollars ($15,000,000), is granted. IT IS FURTHER

ORDERED, ADJUDGED and DECREED that Plaintiffs' motion to determine the Section 41.007 of the Texas Civil Practice and Remedies Code is unconstitutional is denied. IT IS FURTHER

ORDERED, ADJUDGED and DECREED that Plaintiffs' Motion to enter judgment for the full amount of exemplary

damages because Plaintiffs' claim Merrell-Dow has waived the damage limitation of Texas Civil Practice and Remedies Code Section 41.007 is denied. IT IS FURTHER

ORDERED, ADJUDGED and DECREED that Defendant Merrell-Dow's Motion for Judgment Non Obstante Veredicto is denied. IT IS FURTHER

ORDERED, ADJUDGED and DECREED by the Court that Plaintiffs, Ernest and Marilyn Havner, as Next Friends for Kelly Havner, have and recover from Defendant, Merrell-Dow the sum of Twenty Million Two Hundred Five Thousand Eight Hundred Twenty-One and 80/100 Dollars ($20,205,821.80). IT IS FURTHER

ORDERED, ADJUDGED and DECREED that the judgment hereby rendered shall bear interest at the rate of ten percent (10%) simply interest from the date of judgment until paid.

All costs of Court expended or incurred in this cause are hereby adjudged against Defendant, Merrell-Dow. All writs and processes for the enforcement and collection of this judgment or costs may issue as necessary. All other relief not expressly granted herein is denied.

SIGNED on this 1st day of June, 1992.

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Mike Westergren
District Judge Presiding